

Bt Brinjal

A Safe Breakthrough

With environmental clearance from the Genetic Engineering Approval Committee (GEAC) of the Ministry of Environment and Forests in place, Bt-Brinjal has taken an important step towards its widespread cultivation. As is expected, a variety of views, supportive as well as those advocating caution have been expressed regarding the introduction of Bt-brinjal. These concerns carry additional urgency given the fact that brinjal, unlike Bt-cotton, is a food crop bringing in additional issues like consumer choice and labeling.

Mr. Prithviraj Chavan, Minister of State (IC) for Science & Technology and Earth Sciences, Government of India spoke exclusively to Biotech News to highlight the safeguards and rigorous testing that has preceded the GEAC nod to Bt-Brinjal, as well as to allay fears of any downsides to its commercial release.



► **BTN:** Will Bt-brinjal really benefit farmers and consumers? Can you clear the air on the variety of views and opinions that have been expressed in the media, of late?

Prithviraj Chavan (PC): Brinjal is a widely consumed vegetable crop in the tropics with India contributing 20% of global production just behind 30% of China. The crop is ravaged by the Brinjal Fruit and Shoot Borer, or BFSB, the most widespread and devastating pest in India and South and Southeast Asia with infestation inflicting about a 70% crop loss. The larvae feed inside the brinjal shoot and fruits, retarding the vegetative growth of the plant and decreasing the marketability and edibility of the fruit. Countless attempts to crossbreed brinjal varieties with BFSB-resistant wild varieties have been unsuccessful forcing the farming community to rely heavily on chemical pesticides for pest control. The pest population has gradually become resistant to chemical inputs compelling the farmers to resort to combining chemical pesticides, risking human health and the environment in a bid to control the insect.

B. thuringiensis (Bt), a spore-forming bacterium produces crystal proteins (called Cry proteins) which are toxic to many species of insects, including BFSB. When Bt protein is ingested by the insect, it gets activated in the high pH environment of its gut and perforates the lining of the gut, in the process annihilating the insect. The main advantage of this technology is that it reduces the use of chemical pest control making the technology safe for the environment as well as human consumption.

Bt brinjal is based on developing insect resistant crop using Cry1Ac protein from *B. thuringiensis*. Studies show Bt Brinjal requires 70% less insecticide for control of BFSB and 42% less for control of all insects. In addition, yields show a 116% increase in marketable fruit volume and a 166% increase over open-pollinated varieties. Lower pest control costs and higher yields translate into an additional income of Rs. 16,000 - 19,000/acre to farmers, approximately Rs. 2,000 crore for the country as a whole.

Remarkable success of Bt cotton in India, which now occupies 80% of the total area of 9.4 million hectares has clearly demonstrated that adoption of biotechnology can significantly contribute to alleviation of poverty and hunger. In that context, I am sure that development of Bt brinjal, the first biotech vegetable crop, is appropriate and timely.

BTN: Biosafety is a major concern. How has this aspect been tackled in case of Bt brinjal?

PC: Bt crops have been grown around the world since 1996 without any reported adverse health implications. The Cry1Ac protein inserted into Bt brinjal has been extensively studied for its safety. It has been well established that the Cry1Ac protein cannot cause any toxic effect in mammals because of lack of highly specific receptors and acidic environment in the gut. Cry1Ac protein has a history of safe use for human and animal consumption as GM crops containing cry proteins including Cry1Ac protein have been consumed by millions of people without any adverse effects. Cry1Ac protein has shown to be rapidly degraded (in 30 seconds) in simulated digestive fluids and thus is not detectable even in

short term studies. The insecticidal protein is therefore, the safest transgene product for human beings.

Coming to specific case of Bt brinjal, I understand that it has been tested rigorously over the last nine years and has been found substantially equivalent to its non-Bt brinjal counterparts, except for an additional-gene-cry1Ac which expresses Cry protein effective only against very specific target insect in this case BFSB. Cry protein is absolutely safe with respect to all other living organisms including other insects, animals and human beings alike. GEAC has evaluated Bt brinjal for its efficacy and safety as per the protocols and procedures prescribed under the Ministry of Environment and Forest's (MoEF's) Environment Protection Act 1986 and Rules 1989 as well as DBT's own biosafety norms.

GEAC (MoEF) and Review Committee on Genetic Manipulation (RCGM) of DBT have jointly developed protocols for each test, closely monitored progress and ensured compliance during the testing of Bt brinjal. Bt brinjal has been tested extensively at various public sector institutions and nationally accredited laboratories with very good GLP track records in collaboration with Mahyco. Two independent Expert Committees namely the "Expert Committee (EE-I) on Bt brinjal" and "Expert Committee (EE-II) on Bt brinjal Event-I" were set up in 2007 and 2009 respectively to analyze, review and scrutinize biosafety data generated on safety and efficacy of Bt brinjal. Technology developers were asked to strictly adhere to the directives of Hon'ble Supreme Court and ensure compliance. ►►

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► Multi Location Research Trials (MLRT) from 2004 to 2006 were conducted by ICAR and Mahyco separately to generate independent and unbiased data on field performance and assess effect of Bt brinjal on environment. The Large Scale Trials (LST) were assigned independently to Indian Institute of Vegetable Research (IIVR), Varanasi from 2007 to 2009 to generate agronomic performance data, examine efficacy of Bt brinjal on fruit and shoot borer and assess environmental impact. GEAC's independent Expert committee (EE-II) responded to concerns and queries raised by various stakeholders.

Tests conducted so far in various models involving birds, fish, chicken, rabbit, rats, goats and cows have showed no signs of toxicity. Studies have also been conducted for protein expression and quantification, substantial equivalence, nutritional composition and protein estimation on cooked food. All these studies have concluded that Bt brinjal causes no adverse effects when consumed by human, animals, non-target organisms and beneficial insects. In fact, Bt protein was not even detectable in cooked brinjal fruit.

Moreover, the government is actively working on to set up a National Biotechnology Regulatory Authority (NBRA) in the first quarter of 2010, which will ensure that strict scientific assessments are followed while testing of biotech crops. The authority is yet to be passed by our Parliament. Once in place, it will help in a way that biotechnology policies are strictly based on scientific assessment of risk and not on any sloganeering and campaigning by public interest groups.

BTN: Who are the partners in developing this technology?

PC: Bt brinjal has been developed by Mahyco-one of India's leading private sector hybrid seed companies, which has the license for use of Bt cry1Ac gene technology for insect-pest management from Monsanto, USA. This licensed cry gene technology was used by Mahyco to

develop and generate hybrid Brinjal events. The Bt cry1Ac-gene technology was sublicensed by Mahyco to several public institutes in India and South/Southeast Asia. In India, the public institutional partners in the consortium are the IIVR; Tamil Nadu Agricultural University and the University of Agricultural Sciences, Dharwad.

BTN: There is no labeling regime for GM foods in India. Doesn't that deny the consumers the choice regarding consuming or rejecting GM foods?

PC: Labeling of foods containing ingredients produced through the use of modern technology is a complex issue. Crops derived through biotechnology are thoroughly evaluated for food safety, including allergenic potential and nutritional content. Existing evidence suggests that among the developing countries with labeling policies, most have not effectively implemented their regulations, whereas, in developed countries mandatory labeling regulations have resulted in no additional consumer choice or information. Mandatory labeling may result in a higher price for food for consumers in order to meet compliance obligation expenses to food companies. Therefore, it is neither possible nor feasible to label brinjal fruits as GM or non-GM. Since labeling laws are being formulated by the Food Safety and Standard Authority, it is advisable to adhere to labeling regime that is based on the nutritional composition of product and not on the process used to develop the product as long as the product has been determined as safe.

BTN: When will the final decision for commercial sale of BT Brinjal shall be taken?

PC: The GEAC has already declared Bt brinjal Event EE-I safe and recommended the approval for commercial release in its last meeting held in October, 2009 and submitted their recommendation to MoEF. During January and February

2010, they propose to have a series of consultations with scientists, agriculture experts, farmers' organisations, consumer groups and NGOs on the subject. The decision will be made only after the consultation process is complete and all stakeholders are satisfied that they have been heard. The GEAC decision was based on the recommendation of an expert committee, and the committee's report is being made public on the MoEF's website for citizens to comment upon.

BTN: India is the center of origin of brinjal. What are your views on impact of Bt brinjal on genetic diversity of brinjal?

PC: The crossability of different species of brinjal in India has been studied and reviewed. I am given to understand that there is no natural crossing among cultivated and wild species of brinjal including *S. incanum* and *S. insanum*. Under forced crossing situations, even if crossing was possible, the viability and subsequent development of stable crosses have not been successful. Particularly in case of *S. incanum*, the crossability studies have been repeated by Indian Institute of Vegetable Research. It has been indicated that there was very limited crossing when *S. incanum* was used as female parent, whereas in the earlier study (2007-08), no crosses could be obtained. It can be concluded that gene flow from *S. melongena* to wild relatives of brinjal is not possible under natural conditions. Therefore, commercial release of BT brinjal will not in any way affect the genetic diversity of brinjal and its wild relatives. In practice, there are a selected numbers of varieties and hybrids which are popularly grown by farmers to suit consumer's preferences in each zone. The main responsibility to conserve, characterize and utilize diverse germplasm of brinjal lies with our scientific community in developing high yielding and more nutritious varieties by harnessing the potential offered by biotechnology. ■

CALL FOR PROPOSALS

Biotechnology Industry Partnership Program (BIPP) (An Advanced Technology Scheme)

DBT invites proposals from Indian Biotechnology Companies under the Biotechnology Industry Partnership Program (BIPP), a government partnership with industry for support (on a cost sharing basis, mainly for viability gap funding and enhancing existing R&D capacities) for development of novel/ high risk futuristic technologies through varying models of grants, loans or grant cum loan. BIPP has been initiated under Biotechnology Industry Research Assistance Program (BIRAP), a unique initiative of DBT being implemented in partnership with Association of Biotech Led Enterprises (ABLE) and Biotechnology Consortium of India Limited (BCIL) to nurture R&D and innovation in the Biotech Industry. BCIL is the BIPP Management Agency and will ensure maintenance of strict confidentiality of the proposals as per DBT norms.

Key Features of the Program

- Support
 - Large, medium, small scale industry, start ups on cost sharing basis
 - High risk, discovery linked innovation
 - Accelerated technology development
 - Evaluation and validation of biotech products
 - Indigenous discovery, innovation and technology to products
 - Products of national relevance or public benefit

Who can apply?

A single or consortia of Indian "for profit" company(ies) small, medium or large having DSIR* recognized in-house R&D unit(s). An Indian company is defined as one which is registered under the Indian Companies Act, 1956 in which more than 51% of the ownership is held by Indian citizens (including NRIs). The proposals can be submitted:

- Solely by the Indian Company; or
- Jointly by the Indian Company and National R&D Organizations and Institutes; or
- By a group of Indian Companies along with National Research organizations etc.

(* The companies who are in the process of obtaining DSIR recognition may also apply along with the proof of application to DSIR. However, the final decision on such applications would be subject to their getting DSIR recognition.)

Eligible Categories

Category I: Area in health, agriculture, energy and environment with major social relevance but uncertain market driven demand.
Category II: High risk, discovery innovation research including in the area of Biosimilars with relevance for making India globally competitive.
Category III: Evaluation & Validation of already developed products of high National Importance promoting local innovation.
Category IV: Shared cost for major infrastructure facilities, critical for enabling innovation.

How to apply?

The Companies should submit a detailed proposal as hard copies (6 copies; 1 original + 5 copies) and a soft copy in CD (MS Word file-2003-2007 compatible mode, PDF version will not be accepted) strictly in the prescribed format available at DBT website to the following address, on or before 31st December 2009:

The Managing Director
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5th Floor, Anuvrat Bhawan, 210, Deen Dayal Upadhyaya Marg, New Delhi 110 002
Tel.: +91 11 23219064-67 Fax: + 91 11 23219063 Email: bipp.dbt@nic .in

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Last Date for submission of Proposals

31st December 2009

Detailed guidelines for the scheme including eligible project categories to be supported are available at <http://dbtindia.nic.in/AboutBIPP.pdf>