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Genetically Modified (GM) Crops Face an Uncertain Future in India: Bt Brinjal Appraisal – A Perspective

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Abstract: India's hesitant steps into seriously embracing the GM technology in mistakenly addressing an impending food shortage due to an ever increasing population has taken quite a tumble but with mixed results. Its latest attempt in trying to commercialize the first genetically modified vegetable, Bt Brinjal, thus becoming the first GM food crop to be released in India for human consumption went pear shaped when the Union Government of India issued a public moratorium on its approval and commercialization after a series of national consultations in January and February 2010 across India, accounting for the views of over 6,000 farmers, scientists, civilians, government officials and *non*-governmental organizations amidst serious concerns about its inadequately addressed *bio-safety* issues & poor *bio-safety* guidelines followed during GM trials. While arguments have raged both for and against the release of Bt Brinjal for human consumption, the authors' view is that ultimately hopes and aspirations of Bt Brinjal and other GM food crops for commercialization purely rests on sound scientific and social merit rather than political expediencies. This article looks at the current status of Bt Brinjal dispassionately without taking sides and provides a proper perspective to the whole sordid situation.

Keywords: Aubergine, Eggplant, Genetic Engineering, Genetic Modification, Bt Brinjal, *Agrobacterium*-mediated Genetic Transformation, Bt Toxin, *Cry1Ac*, Genetic Engineering Approval Committee, King of Vegetables, Fruit & Shoot Borer

Introduction

Brinjal *or* Eggplant [*Solanum melongena L.*] is an important solanaceous crop of the tropics & *sub-tropics*. The name brinjal is popular in Indian subcontinents and is derived from Arabic and Sanskrit, whereas, the name eggplant has been derived from the shape of the fruit of some varieties, which are white and resemble in shape to chicken eggs. *Solanum melongena L.* is generally known as the brinjal eggplant [1], talong in the *Philippines*, eggplant in the United States of America and aubergine [*French word*] in *Europe* [*Biology of Brinjal, Department of Biotechnology document*].

Across the world, there are around 25 cultivated food species of *Solanum*, a genus of the nightshade family, *or Solanaceae*, which includes potato, tomato and various eggplants [2]. It is a popular vegetable throughout Asia and is both an important vegetable & a vital ingredient in the staple diet of Indians. Amongst low income consumers, it is often considered as a poor man's vegetable as it is used as a very common ingredient of various dishes regardless of social status, income levels & food preferences. Despite this unwelcome connotation, it is also considered "*King of Vegetables*" for its common usage the across social spectra of Indian society [3] [*ISAAA – Revised Pocket K No.* 35]. Despite being low in calories [24 kcal/100 gm] it has high nutrition value, the vegetable has high water content and is a rich source of fiber, phosphorus, potassium, calcium, folate, vitamins B & C. It is also known to have therapeutic value for treating diabetes, hypertension, high blood cholesterol & obesity and is also supposed to block the formation of toxic free radicals. Individuals who are *atopic* [*genetically predisposed to hypersensitivity*, such as *hay fever*] are more likely to have a reaction to *brinjal*, which may be due to the fact that *brinjal* is high in *histamines*. A few proteins and at least one secondary metabolite have been identified as potential *allergens*. Villagers also use dried brinjal plants as fuel for preparing food & other works. The brinjal is known to be consumed both cooked and raw. Some of the most *well-known* brinjal dishes in India include the

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begun bhaja of Eastern India, the *gutti vankaya kura* of Andhra Pradesh, the *katharikai kozhambu* of Tamil Nadu, *upperi* in Kerala, *vangi bath* in Karnataka, *wangyacha bharit* in Maharashtra, *olo, bharatu* in Gujarat and *baingan jhonga* in Bihar. The role of brinjal in religious rituals is best exemplified by one of the traditional varieties in Udupi District of Karnataka called the Mattu Gulla. This particular variety has been cultivated in the region for at least 500 years and is used as an offering to the main deity of the region at the Sode matha temple.

The Center of Origin of Brinjal & Geographical Distribution

The origin of brinjal has been contentious, although, it has been generally believed to have originated in India & hence the genesis of its controversy surrounding the release of GM counterpart is related to its center of origin. It is believed that the probability of *crop-to-gene* flow depends on the geographical distribution of crops & their immediate wild relatives [4]. At all times utmost caution has been exercised in the release of GM crops in geographical regions in which they were known to be domesticated [*i.e.* centers of origin]. Of Vavilov's [1951] eight '*centers of origin*' of crop plants [5], India forms a major part of the Indo-Burma Centre [*inclusive of Assam & Myanmar*], the region in which crops including brinjal have been presumed to have domesticated. Most scientists seem to subscribe to this view and in line with this theory that *Solanum melongena L* is supposed to have originated in India [6]. According to all reliable sources, the belief that *Solanum melongena L* originated in India [6-12] is now strongly validated by archeological evidence [13, 14] which supported the initial domestication of brinjal in north-west India, predating the earliest record of cultivation in East Asia of 59 B.C. [15] by around 2000 years.

In the context of Bt Brinjal controversy, it is alleged that the importance of center of origin is not so much it's precise location, as the contention that brinjal wild relatives can be expected to occur there [16]. The '*center of diversity*' may *or* may not occupy the same location as the center of origin, as crops which were originally domesticated in a certain region may, due to human migration, have been transferred elsewhere [6]. According to Daunay & his group [17] the whole of South-East Asia, from India to China & Indonesia [*including the Philippines*], is the primary diversification center for brinjal eggplant, and the greatest morphological diversity (*i.e.* range of landraces and cultivars) is found there. Within this region, Hawkes (1983) pinpointed India as the '*center of diversity*' for brinjal [18]. Thus there are more than 2500 varieties of brinjal in India of various shapes extending from oval *or* egg-shaped to long *or* club shaped; and colors ranging from white, yellow, green and purple to nearly black. Many popular commercial varieties of brinjal available today are derivatives of older varieties from India and China. According to Zeven and Zhukovsky [1975], it originated in India but spread eastward and by the 5th century B.C. was in China, which became a secondary center of variation [7]. Thus, it has been known for the last 1500 years in China. Arabic traders were responsible for subsequent movement to Africa and Spain. Brinjal cultivation in the Mediterranean region is relatively recent. Later, Portuguese colonies took brinjal to Brazil & other parts of Latin America. It is now widely cultivated for its fruits in the tropical, *sub*-tropical and warm temperate zones, especially, in Southern Europe and the Southern United States. Brinjal has been cultivated in India for the last 4,000 years, although, it is often thought of as a Mediterranean *or mid*-Eastern vegetable. The global area under brinjal cultivation has been estimated at 1.85 million hectares with total production of brinjal fruit of about 32 million metric tonnes [MTs] [19] [*FAO* data, 2005, http://faostat.fao.org/]. India accounts for about 8.7 million MTs with an area of 0.55 million hectares under cultivation. Brinjal is also exported in the fresh *or* frozen form. In 2007-08, 34 million kg worth of Rs. 19 million was exported mainly to UK, The Netherlands, Saudi Arabia and Middle East countries [DGCIS, 2008]. The latest annual crop production figures for Asia region [*in excess of* 37 M MTs*, with a market value of around* $ 8 billion US dollars; *FAO*, 2011) reflect this.

India is the second largest producer of *brinjal* after China, producing 8.7 million tones [26% of the world *brinjal* production] in a land area of 5,50,000 hectares [*Source*: Food And Agricultural Organization of United Nations: Economic And Social Department: The Statistical Division] making it an important cash crop for nearly 1.4 million small, marginal & *resource-poor* Indian

farmers. In India, major brinjal producing states include West Bengal [22%], Orissa [17%], Andhra Pradesh [12%], Gujarat & Bihar [~10% each][http://agriexchange.apeda.gov.in/India%20Production/India_Productions.aspx?hscode=07093000]. Although, brinjal is second only to potato in terms of quantity produced, it continues to be an important domestic crop cultivated across the country accounting for 9% of total vegetable production and covering 8.14% of the land under vegetable cultivation. There are many local varieties in India, in addition to improved varieties and hybrids. Some of the public sector improved varieties include Pusa Kranthi, Pusa Purple Cluster, Syamala *etc*. Hybrids include Arka Navneet, Pusa Hybrid 6, Utkarsha, Pusa Hybrid 5 *etc*. in addition to private sector hybrids.

Brinjal Cultivation in India

Brinjal is a warm season vegetable and susceptible to severe frost. Climatic conditions especially low temperature during the cool season cause abnormal development of the ovary (*splitting*) in flower buds which then differentiate and develop into deformed fruits during that season [20]. The optimum temperature for growth and fruit set is 20-30°C. However the high night and day temperature condition of 22-24°C to 33-35°C markedly reduce fruit set and yield [21-24]. The brinjal can be grown practically on all soils from light sandy to heavy clay. Light soils are good for an early crop, while *clay-loam* and *silt-loam* are well suited for high yield. Generally, *silt-loam* and *clay-loam* soils are preferred for brinjal cultivation. The soil should be deep, fertile and *well-drained*. The soil *p*H should not be more than 5.5 to 6.0 for its better growth and development [*Biology of Brinjal, Department of Biotechnology document*]. Depending on the variety and the season, the average yield of brinjal varies from 15 to 30 tonnes per hectare. Many of the hybrid varieties have shown a potential yield of up to 50 tonnes/ha. The brinjal is generally considered a high value crop yielding high net benefits for the farmer. Studies have shown an *input-output* ratio of 1: 2.01. The total area under brinjal cultivation in 2006 according to the National Horticulture Board was 0.55 million hectares, with a total production of 9.13 million tonnes. In 2007-08, India exported 338 tonnes of brinjal worth Rs.1.92 crores. The United Kingdom is the largest importer (258.84 tonnes worth Rs 1.38 crores) followed by countries like Saudi Arabia, France and Germany.

Figure 1: Different varieties of Brinjal or Aubergine which come in all shapes, sizes and colors

The brinjal eggplant is a shrubby, herbaceous *or semi-woody* plant with a fibrous root system. It grows to a height of 0.5 to 2.0 m with an erect *or* spreading, determinate growth habit. It is a perennial in warmer regions, but cultivated as an annual in temperate regions. Anthocyanin pigmentation, prickles and hairiness on vegetative parts vary widely. The fruit is a pendent, fleshy berry, ranging in color from green, white, yellow, pink, violet to dark purple, with varying degrees of mottling *or* striping on the skin. The shape ranges from spherical, oval, oblong to cylindrical. Fruit size may vary anywhere between 4 to 45 cm long and between 3 and 12cm in diameter, with a weight range of 15 to 1500 g **[Figure 1]**.

The brinjal is usually *self-pollinated*. However, it has been reported that the extent of *cross-pollination* can range from 2% to as high as 48%. It is thus classified as a *cross-pollinated* crop. While the biological structure of the anthers favors *self-pollination*, the stigma projects beyond the anthers, thus providing ample opportunity for *cross-pollination*. The genotype, location, and insect activity further determine the actual rates of natural *cross-pollination*. In spite of its popularity among entire spectra of Indian population & more specifically amongst small & *resource-poor* farmers, brinjal cultivation is

seriously afflicted by two major drawbacks in crop management *i.e.* [1] highly input intensive & [2] pest management. Brinjal is susceptible to many pests and diseases, the most serious and destructive of which is the eggplant fruit and shoot borer (EFSB, *Leucinodes orbonalis* Guenée) and to some extent Fruit Borer [FB] [*Helicoverpa armigera*]. EFSB is a *medium-sized* moth (*Lepidoptera: Crambidae*) whose feeding larvae cause damage to the brinjal crop by boring into stems and fruits. EFSB is a major problem because of its high productive potential & its capacity to evade the common pesticides. The reason EFSB is highly destructive is because of EFSB larvae's ability to bore into tender shoots & fruits, retarding plant growth, subsequently making fruits unsuitable for the market and unfit for human consumption **[Figure 2]**. Fruit damage is as high as 95% and losses up to 70% have been reported in recent times. Yield, therefore, can be affected either by severely damaged *or* destroyed fruits, *or* by damage to the developing plant. EFSB has been described as the most serious and destructive pest to brinjal crops and may cause up to 90% losses in yield [25]. The Report of the Expert Committee (EC-II) on *Bt* Brinjal submitted to the Indian government [26] described losses of between 60-70%, even when insecticides were used. A review of brinjal losses to EFSB in India was given by Andow (2010) and showed that, in fact, losses may be generally overestimated [27]. EFSB damage in India lies anywhere between 5.3-54.8% of the total yield of crop. Losses vary considerably between the various Indian states and between climatic seasons, but seem to average out at around 30% [27]. It is estimated that the damage caused by the EFSB in brinjal [*which has been the major pest for the past two decades or so*] ranges from 50 to 70% and in economic terms, it is estimated to be around US $ 221 million. Although farmers resort to using insecticides, pesticides and other biological control measures, what makes EFSB deadly is that since the EFSB larvae are confined to shoots & fruits, EFSB evades the insecticidal sprays, thereby, becoming a serious menace to *brinjal* production. Farmers in their subjective visual assessment of FSB threat, resort to *over-spraying* the insecticides resulting in an increase in the financial cost of such an exercise. Besides overuse of insecticides also burdens the environment with polluting chemicals and placing human health at risk because of residual effect of these chemicals being present at toxic levels in the fruits. Attempts to develop suitable resistant cultivars through traditional plant breeding have proved futile so far. Keeping these factors in mind, researchers have embraced the biotechnological approach in overcoming this serious pest. Evolution of Bt Brinjal in its initial incarnation is a first step in this exercise.

Figure 2: Brinjal infested with eggplant fruit & shoot borer [EFSB]

Genetically Modified [GM] Crops & Their Concerns

Genetically modified (GM) crops are an important part of sustainable agriculture toolkit, alongside traditional breeding techniques. Proponents of GM technology have tended to mistakenly project genetically engineered (GE) food crops (fruits & vegetables) as panacea for world hunger. Very rarely such claims of GM apologists of increased yields & reduced pesticide usage due to GM technology have any scientific merit in them. In fact, first generation of GM crops was largely irrelevant to poor countries. Overstating the benefits of GM crops will only serve to increase the public distrust of GM technology, as it plays to concerns about the perceived privatization and monopolistic tendencies of *agriculture-based* businesses towards only profits. Nor are science and technology by themselves a panacea for world hunger. Poverty, not lack of food production, is the root cause. The world currently has more than enough food, but some 1 billion people still go hungry because they cannot afford to pay for it.

It has been alleged that GM crops like Bt Maize and Bt Cotton produce higher yields [28, 29] which is in fact grossly misleading. The character *or* attribute that has been incorporated into maize/cotton to make it Bt Maize/Bt Cotton is Bt toxin, an insecticide and as such insecticides cannot possibly increase yields, but only reduce losses by damage limitation exercise. GM crops cannot be a solution to address World hunger, as it is not due to lack of food but due to lack of sufficient buying power. Some research studies have indicated that GM crops required lower pesticide consumption in formative years but pesticide consumption increased after first 3 years by about 4.1% [30, 31]. Besides cost of seeds of GM crops & vegetables were prohibitively expensive when compared to their *non*-GM compatriots thus offsetting perceived benefits of using GM varieties for cultivation.

In the last few years, *Bt Brinjal* has garnered enough newspaper column spaces for all the wrong reasons even before its intended commercial release in India. Being the first genetically modified vegetable crop meant for human consumption, *Bt Brinjal* was rather controversially approved by Genetic Engineering Approval Committee [GEAE] of the Ministry of Environment and Forests in India for the open release of genetically modified Bt-Brinjal (aubergine) plants containing a bacterial gene that produces the *Bacillus thuringiensis* (Bt) toxin, toxic to certain pests, in spite of extensive criticism of the *bio-safety* data that had been provided by the developers Maharashstra Hybrid Seeds Company Limited (Mahyco), the Indian subsidiary of the US-based company, Monsanto. This in a way was supposed to be a significant milestone in India's slow and steadfast embrace of *agro-biotechnology* with *Bt Brinjal*'s nod for approval coming nearly 11 years after the release of *Bt Cotton* as India's first genetically modified [GM] crop, harboring grandiose ambitions of another Green Revolution in India. In the light of the comments received by Mr Jairam-RAMESH, Union Minister of Environment and Forests in India and a series of national consultations in January and February 2010 across India, accounting for the views of over 6,000 farmers, scientists, civilians, government officials and *non*-governmental organizations, Mr. Jairam-RAMESH, placed an indefinite moratorium on the release of genetically modified Bt-Brinjal on 9 February 2010. Some of the reasons included

(a) Inadequately addressed *bio-safety* issues concerning environment & public health.
(b) Appalling application of international *bio-safety guidelines* while conducting safety tests,
(c) Complete lack of transparency in sharing test results, their implications to seed sovereignty of farmers, and
(d) Inherent lack of informed choice for the consumers.

Evolution of Bt Brinjal

Brinjal is adversely affected by eggplant fruit & shoot borer [EFSB, *Leucinodes orbonalis* Guenée] and to some extent Fruit Borer [FB] [*Helicoverpa armigera*]. These insect pests cause about 60-70% loss in commercial plantings [32]. As pests remain larvae hidden within both roots & shoots, application of insecticides remains largely ineffective resulting in not only in indiscriminate usage of insecticides to the point of toxicity of the crops besides making the whole exercise of crop production way too expensive. Damage starts in the nurseries prior to transplanting, continues up to harvest and is then *carried-over* to the next crop. ESFB damages brinjal in two ways; firstly, it infests young shoots during vegetative phase which limits the ability of plants to produce healthy fruit bearing shoots, thereby, reducing potential yield; secondly, it bores into fruits during reproductive phase making them unmarketable. To counter these inefficiencies, a transgenic version of Brinjal was developed by inserting *Cry1Ac* gene from soil inhabiting Gram-positive bacterium, *Bacillus thuringiensis*, which was discovered by a Japanese biologist Shigetane-ISCHIWATA in 1901 [33]. To understand the process of creation of *Bt Brinjal* one must first understand Bt itself. *Bacillus thuringiensis* [Bt] is a *naturally-occurring soil-borne* bacterium that is found worldwide. A unique feature of this bacterium is its production of *crystal-like* proteins that selectively kill specific groups of insects. These crystal proteins [*Cry* proteins] are insect stomach poisons that must be eaten to kill the insect. Once eaten, an insect's own digestive enzymes activate the toxic form of the protein. The *Cry* proteins bind to specific "*receptors*" on the intestinal lining and rupture the cells. Insects stop feeding within two hours of a first bite and, if enough toxins

are eaten, die within two *or* three days. There are several strains of Bt, each with differing *Cry* proteins. Scientists have identified more than 60 *Cry* proteins. Proteins have been found with insecticidal activity against the *Colorado potato beetle* [for example, *Cry3A*, *Cry3C*], *corn earworm* [*Cry1Ac*, *Cry1Ab*], *tobacco budworm* [*Cry1Ab*] and *european corn borer* [*Cry1Ab*, *Cry1Ac*, *Cry9C*]. Since GM technology is still in its infancy at least in India, it is grappling with worrisome issues of unpredictability & imprecision.

Generally, the process of development of any genetically modified [GM] crops involves two stages. In the first stage, gene of interest is inserted & integrated into the chromosome of the target crop (*host*) using recombinant DNA technology where the host is now considered to be transformed. The gene can be inserted in to two ways – either by *Agrobacterium*-mediated method *or* gene gun method as shown in **Figure 3**. Transformed host cells are then developed into whole plants using plant tissue culture techniques. In the second stage, gene from the transformed variety [*which is not agriculturally suitable*] is transferred to a hybrid [*agriculturally suitable*] by plant breeding techniques [*as shown in* **Figure 3**] and the hybrid can then be released for commercial cultivation.

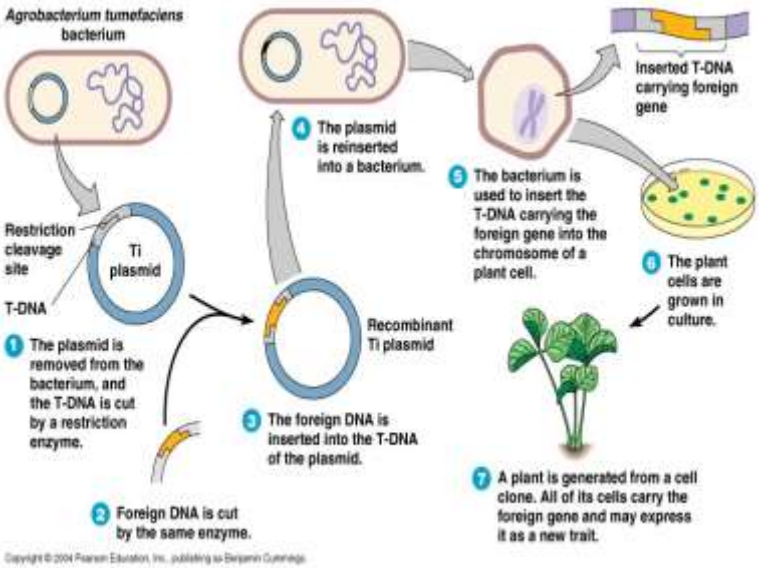

Figure 3: *Agrobacterium tumifaciens* mediated Genetic Transformation in Plants

The process of development of Bt Brinjal followed the same procedure and took about 9 years to complete. Gene isolation & integration [*transformation*] was started in the year 2000 and the hybrid was ready for cultivation by 2002. Bt Brinjal has been developed by inserting a gene *Cry1Ac* from a soil bacterium called *Bacillus thuringiensis* through an *Agrobacterium*-mediated gene transfer. It is a genetically modified brinjal developed by the Maharashtra Hybrid Seed Company Ltd. (Mahyco), a leading Indian seed company. Bt Brinjal event EE1 has been developed in a *Public-Private* Partnership mode under the aegis of the Agriculture Biotechnology Support Project from Cornell University where the Bt technology available with M/s Mahyco has been transferred (*free of cost*) to Tamil Nadu Agriculture University, Coimbatore, University of Agricultural Sciences, Dharwad and the Indian Institute of Vegetable Research, Varanasi.

Bt Brinjal contains three foreign genes which have been inserted namely:

1. The *Cry1Ac* gene which encodes an insecticidal protein *Cry1Ac*, is derived from common soil bacterium *Bacillus thuringiensis* (Bt) *subsp*. *kurstaki* to produce the insecticidal protein. The *Cry1Ac* gene is driven by a viral promoter, the cauliflower mosaic virus (CaMV) 35S promoter.
2. The *nptII* gene for an antibiotic resistance marker, neomycin phosphotransferase-II.
3. The *aad* gene for another marker 3" (9) *O*-aminoglycoside adenyl transferase.

Expression of *Cry1Ac* gene said to give the Brinjal plant an effective *in-built* resistance against lepidopteron insects like the Eggplant Fruit and Shoot Borer [EFSB] [*Leucinodes orbonalis*] and Fruit Borer [FB] [*Helicoverpa armigera*]. When ingested by the FSB/FB larvae, the *Cry1Ac* protein is activated in their alkaline gut and binds to the gut wall, which breaks down allowing the Bt spores to invade the insect's body cavity. Subsequently, the EFSB/FB larvae die within a few days following disruption of their digestive processes, thus preventing the menace of FSB & impending financial loss to famers.

How is the Bt Brinjal effective against pests like the eggplant fruit and shoot borer [EFSB]?

When eggplant fruit and shoot borer [EFSB] larvae feed on Bt Brinjal plants, they ingest the Bt protein *Cry1Ac* along with plant tissue. In the insect gut which is alkaline with a *p*H > 9.5, the protein is solubilized and

activated by gut proteases crystallizing into fine *needle-like* shards that pierce the insect gut lining making holes in it. This leads to disruption of digestive processes, paralysis and subsequent death of the fruit and shoot borer larvae.

Chronology of Development of Bt Brinjal

2000: Transformation and greenhouse breeding for integration of *Cry1Ac* gene into brinjal hybrids and seed purification.

2001-2002: Preliminary greenhouse evaluation to study growth, development and efficacy of Bt Brinjal.

2002-2004: Confined field trials to study pollen flow, germination, aggressiveness and weediness; biochemical, toxicity and allergenicity studies and backcrossing into the regular breeding program.

2004: Review Committee on Genetic Modification (RCGM) approves conducting *multi-location* research trials of seven Bt Brinjal hybrids

2005: Through a memorandum of understanding (MoU) under the aegis of Agribiotechnology Support Program II (ABSP II) of USAID Mahyco shares the technology with TNAU, DAU and IIVR to develop open pollinated varieties of Bt Brinjal. Back crossing and integration of EE1 into 4 varieties of TNAU, Coimbatore and 6 varieties of UAS, Dharwad is done.

2004-05: *Bio-safety* data on the effects of Bt Brinjal on soil *micro-flora*, efficacy against eggplant fruit-shoot borer, pollen flow, germination, aggressiveness and weediness; toxicity and allergenicity studies, chemical composition *etc*. submitted to the Review Committee on Genetic Modification (RCGM). RCGM recommends large scale trials to the GEAC.

2006: Mahyco submits *bio-safety* data to Genetic Engineering Approval Committee (GEAC) and seeks permission for large scale trials.

- GEAC posts the *bio-safety* data on Bt Brinjal on GEAC website
- GEAC constitutes a *sub-committee* to look into the concerns raised by civil society.
- Supreme Court stops ongoing field trials of GM crops due to a PIL filed by civil society representatives.

2007: The *sub-committee* [*expert committee* 1] submits its report, recommends that 7 more studies on *bio-safety* be repeated for reconfirmation of data generated during confined *multi-location* trials but gives a green signal for large scale trials.

- Supreme Court lifts ban on GM crop field trials subject to conditions such as isolation distance *etc*.
- GEAC approves large scale trial.
- As per GEAC direction, Indian Institute of Vegetable Research [IIVR] takes up the responsibility of large scale trails of Mahyco's Bt Brinjal trials at 10 research institutions across the country in 2007 and 11 in 2008.

2009 January: IIVR submits the results of the large scale trials. Due to concerns raised by several stakeholders including some national and international experts, GEAC constitutes a 2nd *sub-committee* [Expert Committee 2 *or* EC2] to look into adequacy of biosafety data generated as well as the concerns raised by all stakeholders.

2009 October14: The *sub-committee* submits its report based on which GEAC approves the environmental release of Bt Brinjal containing the event EE1.

2009 October 15: Responding to strong views expressed both for and against the release of the Bt Brinjal, the Minister of State for Environment and Forests (I/C) (*to whom the GEAC reports*) announces a nationwide consultation in January and February of 2010 pending a final decision on this issue.

2010 February 9: Indefinite moratorium on commercial release and cultivation of Genetically Modified Bt Brinjal imposed by the Minister of State for Environment & Forests, Union Government of India.

Marginal Benefits & Overriding Concerns of Bt Brinjal

Bt Brinjal definitely led to a significant reduction in the usage of pesticide by 80% as against the normal scenario when *non*-Bt Brinjal was grown. However, no difference was noticed with respect to susceptibility to various pests and diseases by virtue of presence of *Cry1Ac* gene in Bt Brinjal. In *multi-location* and large scale trials conducted by Mahyco (2004-08) [32] Bt Brinjal hybrids were found to be highly effective against fruit & shoot borer larvae as against *non*-Bt counterparts. Despite these obvious benefits, some serious concerns have been expressed with Bt Brinjal. Most significantly, Mahyco used an older protocol developed in 1995 by Fari & *co-workers* [34] for Bt Brinjal overlooking newer methods in GM technology available at that time. The plasmid used (*p*MON10518) in the Bt Brinjal gene transfer has antibiotic resistance markers for *kanamycin* (*nptII*), *streptomycin* (*aad*) and a 35S CaMV promoter (*to assist in expression of these genes*). A part of the base sequence of 35S CaMV resembles some sections of HIV AIDS virus [35] while kanamycin & streptomycin are important drugs among handful in our armory to fight tuberculosis [36]. Any gene manipulation involving the insertion of foreign DNA sequences into a plant genome can cause disruption, silencing *or* modification of the expression of existing

genes. Some effects may be anticipated, but, others may come as a complete surprise [37].

It is worrisome that Mahyco has overlooked public communication about the potential risks in this technology. It was recognized that the recombinant DNA has the capacity to cause gene contamination by jumping into other species. It has also been observed that the amino acid sequence of all *Cry* proteins in Bt crops have sequence similarity to known allergens and hence *Cry1Ac* could act as a possible allergen. The gene inserted into Bt Brinjal has the possibility to survive digestive processes and can be absorbed into the human body. They can also transfer themselves into intestinal bacteria. Laboratory studies have also shown that the *Cry1Ac* has both immunogenic and adjuvant capacities [38].

One of serious concerns raised about GM crops in general is that the testing requirements for GM crops are not as stringent as required for new drugs. While new drug trials are conducted exhaustively in 5 different stages, with the first stage of *pre-clinical* studies involving animals with remaining stages dealing with safety and efficacy issues in humans. Governmental guidelines for research in GM crops *or* transgenic plants only require toxicity (with testing periods of 14-90 days) and allergenicity tests (with testing periods of 14-37 days) [39]. It does seem bizarre that regulations for transgenic product meant predominantly for human consumption does not include a battery of tests involving humans to determine *bio-safety* features of the product. Although the guidelines stipulate that experimental data related to toxicity and allergenicity to humans & animals must be generated and corroborated by the GM developer, Mahyco's toxicology studies have been solely performed on animals and therefore, it is equivalent to the *pre-clinical* studies that are undertaken for drug trials. Results of toxicology & *bio-safety* tests & safety guidelines undertaken to generate this information has invited widespread criticism amongst experts and independent arbiters of transgenic research.

French scientist Prof. Gilles Eric Seralini, President of the Committee for Independent Research and Information on Genetic Engineering [CRIIGEN], who carried out the first ever independent assessment of *Monsanto-Mahyco's* dossier on toxicity tests submitted to the Indian regulatory authorities at the behest of Greenpeace India was clearly unimpressed with the guidelines followed in toxicology trials as well as with the quality of data generated. Based on the experimental data suggested he certified that release of Bt Brinjal represented a serious risk to human & animal health and the environment and therefore not fit for human consumption. On health aspects of toxicology tests, Prof. Gilles Eric Seralini, found that

(a) Bt Brinjal produced a protein in the vegetable cells that induced antibiotic resistance. This was recognized as a major health problem and was inappropriate for commercialized use.
(b) Bt Brinjal had 15% less calories and different alkaloid content compared to *non*-GM Brinjal.
(c) When fed to animals, adverse effects were observed on blood chemistry with significant differences according to the sex of the animal *or* period of measurement. Other effects were on blood clotting time [*prothrombin*], total bilirubin [*liver health*], and *alkaline phosphate* in goats and rabbits.
(d) Changes in lactating cows were observed in increased weight gain, intake of more dry roughage matter and milk production up by 10-14% as if they were treated by a hormone.
(e) Rats fed Bt Brinjal had diarrhea, increased water consumption; decrease in liver weight, and liver to body weight.
(f) Feed intake was modified in broiler chickens.

According to Prof. Gilles-Éric Séralini, "*This makes for a very coherent picture of Bt Brinjal that is potentially unsafe for human consumption*. *The GM brinjal cannot be considered as safe as its non-GM counterpart*." In addition, he said that the longest toxicity test were only for 90 days, which did not assess *long-term* effects such as the development of cancers *or* tumors. Furthermore, he considered it potentially unsafe to eat animals with the health problems that had been fed Bt Brinjal.

Bt toxins are derived from the soil bacterium *Bacillus thuringenesis;* natural Bt toxins have never been authorized for mammalian consumption and are known to be harmful to health [40]. The *half-life* of

Cry1Ac protein in plant tissue is reported to be 41 days, which could then persist in the soil. Hence, more studies are needed to understand the impact of Bt toxin on microbial ecology of the soil. Prof. Gilles Eric Seralini,'s appraisal also cautioned against synthetic and genetically modified Bt toxins such as the hybrid toxin contained in Bt Brinjal that mixed two toxins, the *Cry1Ab* and *Cry1Ac* engineered sequences together. A serious flaw in the *Monsanto-Mayhco* toxicity tests on *non-target* insects was that tests were conducted on a surrogate protein rather than the modified hybrid version of *Cry1Ac* used in Bt Brinjal because this was easier than the hybrid.

Another independent reviewer, Dr. Lou M. GALLAGHER, who advises the New Zealand government, universities & the private sector on matters of toxological risk assessment, *dose-response* modeling and environmental epidemiology related to GM crops was even more scathing in her assessment of Monsanto-Mahyco report. This independent evaluation of Bt Brinjal studies is based on requirements for a rigorous evaluation of food safety for the people of India and their health. This study suggested that departures from Indian and internationally published standards for the 14-day and 90-day studies were a serious cause for concern. The food safety studies for Bt Brinjal were not conducted in accordance with internationally published standards, did not accurately summarize results, and ignored toxic endpoints for rats fed Bt Brinjal: in particular, rats fed Bt Brinjal for 78 out of 90 days (only one dose level) experienced:

(a) Organ and system damage: ovaries at half their normal weight, enlarged spleens with white blood cell counts at 35 to 40 percent higher than normal with elevated eoisinophils, indicating immune function changes.
(b) Toxic effects to the liver as demonstrated by elevated bilirubin and elevated plasma acetylcholinesterase.

Major health problems among test animals were ignored in these reports. The single test dose used was lower than recommended by the Indian protocols. Dr. Lou M. GALLAGHER suggested that release of Bt Brinjal for human consumption could not be recommended given the current evidence of toxicity to rats in just 90 days and the studies' serious departures from normal scientific standards. Dr. Lou-GALLAGHER was also of the view that toxicological tests were severely compromised as neurological function, behavioral effects, reproductive performance and biological resilience of test animals were not evaluated in these studies. Dietary equivalence of dried brinjal, dried Bt brinjal and control diets was not addressed. Concentrations of the new insecticide protein *Cry1Ac* were not measured in dried brinjal powder.

The use of laboratory animals to test food safety, although, widely accepted as a toxicological tool, is only an indication of effects that might be expected from human exposure. It is essential that deviations from standard protocols be evaluated carefully, as these changes can have a profound impact on results. Yet every departure made by INTOX (*the laboratory contracted to do the research*) from the Department of Biotechnology, INDIA protocol (1998) resulted in lower standards being used, with less power to detect changes in rats eating Bt Brinjal. These included: skipping important endpoints such as *Ig*E measurement to test for *allergenicity*, testing only one dose that was lower than human consumption is likely to be, ignorance of *toxicological equivalence*, lost data, lack of Good Laboratory Practice (GLP) standards, inadequate observation of animals, a 29% decrease in exposure days in one study (*doses were administered* 5 *days per week instead of* 7) *etc*. Besides dietary equivalence for Brinjal-fed rats, Bt Brinjal-fed rats and vehicle control rats was not addressed in these tests. The tests also did not show the issue of inhalation exposures to people who grow Bt brinjal *or* live near Bt Brinjal crops in the ground. Toxicological responses to proteins that reach the lining of the lungs and nasal cavity, previously found to be of concern for agricultural workers, have not been addressed. Consequently, the studies submitted by Mahyco are woefully inadequate to determine the safety of Bt Brinjal for *long-term* human consumption. The evaluation report was also critical of the substandard and extremely misleading interpretation of results suggesting the reviewer to implement urgent changes to ensure that future studies were properly conducted and interpreted.

In addition, there have been other shortcomings in Mahyco’s biosafety testing

procedures adopted for Bt Brinjal. The pollen flow studies done were unreliable as they were done in only one season at a couple of locations where 146% and 27% outcrossing were reported. More studies needed to be done in the more locations in several seasons for accurate assessment of data. The available data seemed to suggest the likelihood of outcrossing from GM crop was more compared to its *non*-GM counterpart. Majority of the tests such as, pollen flow studies, *Cry1Ac* protein expression, baseline susceptibility, protein estimation in cooked fruits, soil analysis, other equivalence studies were taken up by the company promoting Bt Brinjal. Of the various tests, only 4 tests were conducted by public sector institutions. Unfortunately, there is no internationally accredited independent regulatory authority exits in India to thoroughly conduct and verify the tests related to GM crop trials.

According to the report of the Independent Expert Committee on Bt Brinjal chaired by Dr. K. P. PRABHAKARAN-Nair, the members stated that they were not sure whether testing laboratories were accredited and followed standard GLP practices. It was not even clear how the materials were ascertained and whether they were authentic. The committee was constrained to by the lack of experiment details [*protocol*, *full data*, *statistical evaluation etc*.] to critically examine the issues involved. In fact, in many instances only the summary of reported work carried out was available. The committee also had a poor view of Mahyco's agronomic trials and other tests related to pollen flow, aggressiveness *etc.* as they did not follow best agronomic & pest management practices already existing elsewhere in the country. Other points observed by the committee were

(a) No statistical analysis was done in reports by the company. Without statistical analysis no meaningful conclusions can be drawn.
(b) Data on the number of (*pesticide*) sprays, quantity of fertilizer used and the type of fertilizers used for the different treatments were not available.
(c) No information on the plant population at the time of harvest was available. This was extremely crucial for a reliable statistical scrutiny.
(d) It was also not clear who had taken the count of various pests, insects, diseases *etc*., from the trial plots and who has supervised data collection from the farmers' fields.
(e) Data were not been presented along with the checks and the *non*-Bt counterparts. Selective presentation of data was noticed.
(f) The company tasked to undertake the trials was asked to follow *Cry1Ac* protein expression once in 15 days which was not meticulously followed.
(g) The committee was also unable to locate any data on the economics of pesticide use, the cost-benefit ratio, as required to be generated from all trial locations as per the DBT's permission letter in 2005. In the absence of all such data, no valid and dependable conclusion could be drawn on the efficacy of Bt Brinjal.

The committee was generally unhappy at the shoddy manner in which trials were conducted and haphazard manner in which reports were generated & hence they expressed serious concerns about the GM trials and based the evidence provided the committee was not sure if Bt Brinjal was fit for human consumption.

Dr. Judy Carman, Director of The Institute of Health and Environmental Research Inc. (IHER). A *not-for-profit* research institute with an interest in genetically modified (GM) organisms, particularly those destined for food also provided a scathing review of the Mahyco trials of Bt Brinjal. Summarizing her review, she stated that the information submitted by Mahyco was completely inadequate to determine if the composition of Bt Brinjal was similar *or* different to ordinary brinjal under all experimental conditions. Moreover, the information presented was inadequate & did not meet the accepted scientific standards of reporting regarding proteomic profiling, allergenicity assessments, reproductive studies, digestive studies, animal feeding studies & acute toxicity studies in animals. Finally IHER's assessment was that Mahyco had conducted a number of studies to show that Bt Brinjal was safe to eat, however, none of the studies were of any real use, for the following main reasons:

(a) The type of studies undertaken was insufficient to determine whether Bt Brinjal was fit for human consumption.
(b) Of those studies undertaken, the methodology and results were often

insufficiently reported to be able to determine what the studies were actually was measuring *or* how various variables were measured. Included in this, the statistical results were not reported to a suitable standard. For example, means, standard deviations, and *p*-values, which would be required for any *peer-reviewed* scientific journal, were usually omitted.

(c) The sample sizes were insufficient to be able to find statistical difference for many measurements even if real clinical differences were occurring between groups. Indeed, much of the research presented by Mahyco could be regarded as being burdened with *Type II* error. This type of statistical error occurs when sample sizes are so low that the study cannot realistically be expected to find a difference between groups of animals even if clinical differences are occurring. So, when Mahyco finds no statistical difference between the compositions of Bt Brinjal compared to *non*-Bt Brinjal, *or* measurements on GM-fed animals compared to *non*-GM-fed animals, and touted this as showing that Bt Brinjal would not cause harm to those that ate it, they were likely to be wrong. The lack of statistical significance was much more likely to be simply due to testing too few samples (*for composition*) and too few animals (*for health effects*).

Besides there is a serious issue of effect of Bt Brinjal on biodiversity of Brinjal. India is responsible for the origin of aubergine cultivation for nearly 4000 years, with more than 2,500 varieties, one of which has even been registered under the Geographical Indication clause of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), ensuring authenticity of this variety. All international covenants clearly state that if a country is the center of origin for a particular crop, that crop shall not be genetically engineered in that country [41]. The Genetic Engineering Approval Committee (GEAC) under the control of Indian Ministry of Environment and Forests is responsible to regulate research, testing and for commercial release of GM crops, foods and organisms. In 2006 the Government granted permission to the Maharashtra Hybrid Seeds Company Limited (Mahyco), acting under license from the global seed giant Monsanto, to carry out field trials for Bt Brinjal in India. This decision itself was against Convention of Biological Diversity & Cartagena Protocol on *Bio-safety* which discourages the genetic modification of crops in their land of origin. The Cartagena Protocol calls for extreme caution in introducing GM crops to countries which are the centers of origin for the *non*-GM varieties of those crops. The protocol was a part of an international treaty adopted in Rio de Janeiro in June 1992 to protect biodiversity. Therefore, doubts are raised about experimenting with Brinjal on its home ground, India.

Apparently, it is alleged by experts that India does not need Bt Brinjal, as India produces enough aubergines in a legion, besides being the cheapest and widely consumed vegetable in India after potato. It is alleged that under GM trials up to 30 tests should be carried out to ensure *long-term* biosafety of a GM crop [*as recommended by* Dr. Pushpa M. BHARGAVA, *founder Director of CCMB, Hyderabad & Former Member of the National Security Advisory Board, Government of India*] before releasing the GM organism in nature; these include long term consumer and environmental toxicity testing and complete proteomic profiling of the GM crop against its *non*-GM counterpart. However, in the case of Bt Brinjal, the dataset did not include a complete analysis using these tests.

It has also been pointed out by experts in the field that according to Monsanto's data, aubergine pollen can travel for up to 30 meters. In India, 84% of farmers (*who account for* 62% *of the Indian population*) are small holders with less than 4 hectares of land. Aubergines are grown almost exclusively by these farmers, mostly in plots measuring less than an acre. To leave 30 meters around the plot to prevent contamination of a field by Bt Brinjal from an adjoining plot, would leave virtually no space for cultivation! Besides in India there are no liability laws to protect the interest of organic farmers in case their farms/lands are contaminated by the GM crops grown in a neighboring farm. Since there are neither labeling laws for GM crops in India as against what is found in majority of countries nor any kind of awareness programs conducted to explain the nature of GM foods & the need for labeling them, it would be extremely difficult to segregate GM crop from its *non*-GM counterpart once GM crop is released into environment. Besides, once the GM crop is

released, it cannot be recalled as it would have already mixed with the natural germplasm of the crop. Every Indian has a right to an informed choice about what he is consuming *or* eating in his staple diet. This right is enshrined in India's Consumer Protection Act and the GEAC approval will violate the provisions of this act. Further, labeling is not just about pasting a colored sticker on a brinjal, it involves a rigorous process of segregation and identity preservation [IP] to keep Bt and *non*-Bt food segregated. IP is a complex and expensive process requiring separation of a GM food from *non*-GM food, starting from farmers' fields, all the way to vegetable shops. Without going through this process, labeling cannot be done. As a result safety assessment of Bt Brinjal need to be determined thoroughly taking all aspects of agronomic, environmental, human, soil & animal health, *socio-economic* impact, genetic diversity into account.

Was the Bt Brinjal Biosafety Studies Severely Compromised?

For all the obvious benefits of GM crops in general & Bt Brinjal in particular, which, in some circles, has been touted to merely promote the global seed markets, biotech companies & crush local small scale farmers [42], serious evidence has been mounting against GM crops' research and it has not been helped by the slipshod manner in which the dossier of Monsanto-Mahyco safety studies was created. Some science organizations and Greenpeace activists have alleged that dossiers of Monsanto-Mahyco *toxicity-safety* studies may have been severely compromised based on the independent appraisals of the reports submitted. French scientist Prof. Gilles Eric Seralini, President of the Committee for Independent Research and Information on Genetic Engineering [CRIIGEN], one of the first independent reviewers of the dossier found serious discrepancies in the safety tests between Bt Brinjal and *non*-Bt Brinjal which though significant were biologically irrelevant & hence was not investigated further. Prof. Gilles Eric Seralini, was also not impressed with the quality of data generated, sample size used & failure to adhere to GLP practices in all the tests conducted. Similarly, Dr. Lou M. Gallagher, another independent reviewer was of the view that safety claims of the dossier were not supported by the data provided. Furthermore, the clear signs of organ and system damage in the group of animals fed on BT Brinjal were "*airbrushed out*" and Dr. Lou M Gallagher, clearly suspected that the conclusions to the studies were not written by the original research teams, but by Mahyco, who paid for the studies. She noted that it was not just the conclusions that are at variance even the text did not match the experimental data, and the researchers did not personally sign off their reports as against standard operating procedures (SOPs). Dr. Judy Carman, Director of The Institute of Health and Environmental Research Inc. (IHER) suggested that dossier submitted by Mahyco was completely inadequate to determine if the composition of Bt Brinjal is similar *or* different to ordinary brinjal under all experimental conditions. Moreover, the information presented was inadequate & did not meet the accepted scientific standards of reporting regarding proteomic profiling, allergenicity assessments, reproductive studies, digestive studies, animal feeding studies & acute toxicity studies in animals. Prof. Aujula Reddy, Chairman of Genetic Engineering Approval Committee (GEAC) recently confessed to have been coerced into approving Bt Brinjal for national release by Agriculture Ministry, GEAC and GM industry. Based on the collective evidence collected across the spectrum of Indian public, an Indian Parliamentary panel in Aug 2012 urged the Union Government to halt all *open-field* trials of transgenic crops until it develops a better system of monitoring & oversight. The panel recommended a clear overhaul of the regulatory system wanting it to be an independent body of experts without any conflicts of interest either with pesticide *or* GM industry [43]. The panel in its 389-page report suspected a "*collusion of interests of the worst kind*" behind the approval after recent confessions of complicity from the chairman of GEAC.

A major reason why Bt Brinjal in India has courted so much controversy is because of hasty manner in which it was approved for commercial release by the GEAC whose members while trying to review the Monsanto-Mahyco dossier were also masquerading as promoters of their own commercial interests and the interests of seed companies. In this scenario, "*conflicts of interests*" of some of the members of GEAC are all too apparent which has been validated to an extent by the revalations of chairman of GEAC. It has also been alleged in some circles

that the regulatory system on GM crops in India is not independent & internationally accredited to deliver objective reviews on GM crop trials and is subservient to US interests with both Indian Council of Agricultural Research (ICAR) and Department of Biotechnology (DBT) being guided by the principles and interests of US Artificial Insemination Department (USAID) ever since the Indo-US Knowledge Initiative in Agriculture, Research and Marketing (KIA) was put into place (*almost at the same time the nuclear treaty was signed*), the ICAR does exactly what the USAID wants it to do. The international debate on GM crops is highly polarized between its proponents & critics. Given this stance and the fact that Bt Brinjal could become World's 1st food crop to be commercialized for human consumption, the stakes could not be any higher. Given the polarization of views and the fact that genetic modification relies purely on technology, scientific evidence becomes essential and establishing credibility amongst the general public becomes paramount. What has halted Bt Brinjal in its tracks is that top international scientists have certified the *bio-safety* studies to be unprofessional, unscientific and false. Tests and their results have not been verified by independent authorities & risks to human health, animal health, environment & plant biodiversity cannot be ruled out.

Is There a Need for Bt Brinjal in India & What is the Future for GM Crops?

It has been pointed out by many a scientist that India being the center of origin for brinjal, produces enough quantities of the same under nearly 2500 varieties; it is the cheapest & most widely consumed vegetable available in India after potato. According to Dr. Pushpa-BHARGAVA [41], the damage by pests to aubergine crops in the country is marginal and there are several alternatives for crop management – such as integrated pest management, use of biopesticides and organic agriculture. In the state of Andhra Pradesh alone, there are 2 million acres under organic agricultural cultivation. This area will most probably increase to 10 million acres in the next few years, as a part of the State Government's policy. Prof. ARJULA-Reddy was of the view that knowing brinjal's antecedents, Bt Brinjal's entry point itself is suspect as it was being aggressively promoted at the behest of American interests to bending India's agricultural policies through the joint Indo-US Knowledge Initiative Commission set up by the Prime Minister of which Monsanto & Dow Chemicals are permanent members who are too happy to push their points of view. While genetic engineering is a precise science, it's effects in plants are not so precise as one needs to rely on traditional plant breeding mechanisms to see the desired effect of gene transfer and hence it makes the process unpredictable. Currently, in plants, genetic engineering can be successfully performed by one of the two available methods (i) Gene gun method (ii) Plant cancer method mediated thro' soil bacterium *Agrobacterium tumifaciens*. The uncertainty of the technique is the reason why one uses antibiotic marker genes to separate the cells whose genome absorbed the foreign gene from those which do not. The rationale behind development of Bt Brinjal is based on a rather false premise that genetically engineered Bt Brinjal is viable alternative to use of chemical pesticides for pest control. One of the other alternatives to chemical agriculture, organic farming based on principles of *agro-ecology* has not been considered. It is suggested by most experts in the field that the time is ripe to overhaul the regulatory process for GM trials & interdisciplinary *bio-safety* assessment systems which are free from motivated campaigns of both biotechnology & pesticide industries through multinational corporations (MNCs). The other major concern of the public is given the unpredictability of science involved, can the research conducted by private companies to promote their own agendas be trusted. Currently, as we know that all research is funded by private companies and then presented to the regulators for clearance. It is not surprising then that there is an enormous lack of 'credibility' - people do not believe what they say has been done. And given the horrific and scandalous track record of private research misguiding policy in the case of drugs *or* food, such apprehensions are understandable. Instead, a new system where research must be publicly funded and openly scrutinized. The money must come from companies, but in the form of a cess collected into a fund and accountability for research involving that money can be established. The most fundamental reason being that every human being has a right to make an informed choice whether to consume Bt Brinjal *or* not which is also complicated by the fact that India does not have labeling system to segregate GM from *non*-GM crops. This is also accentuated

by the labeling demands that the country must have a laboratory network and an independent & internationally accredited functioning regulatory system, so that GM-content can be analyzed and told to consumers. Besides, not knowing the effect of release on plant diversity will further be a dampener for its approval. All in all in its current status, Bt Brinjal is not worth the risk and uncertainty it presents. This is not a verdict on GM crops, but a verdict on a vegetable that we want our choice to eat *or* not to eat. Till a foolproof system to evaluate the safety of Bt Brinjal for human consumption is established, general public & farmers will always be skeptical of embracing the GM technology for all its perceived benefits. In the current uncertain scenario, Bt Brinjal and other GM crops' research face an uncertain future till an independent & internationally accredited regulatory system [*free of bias of either pesticide or GM industry or political affiliation*] for assessment of toxicity, allergenicity, *bio-safety*, agronomic worth, human health, animal health, ecological health, plant diversity *etc.* before recommending it to be fit for human consumption.

Commercialization of *Bt Brinjal* (*or* any other food crop) will be an important milestone for Indian agriculture as it'll be the first GM food crop in the World to be released in its habitat of origin for human consumption. Its potential implications are too massive to even comprehend as it will open flood gates for more transgenics already in the pipeline for development to gatecrash into the market to reap the misplaced benefits of modern biotechnology which at this point in time is a hit & miss at the best. But, much will depend on how people accept *Bt Brinjal* based on pure scientific & social merits of the case and how it will impact their lives in the long run. Hence, no stone should be left unturned to get all regulatory checks for its testing in place before it is released into the public domain for human consumption.

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