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COMMENTS

Should the Bt Brinjal controversy concern healthcare professionals and bioethicists?

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Abstract

The Genetic Engineering Approval Committee's approval of Bt brinjal, the first genetically modified crop for human consumption in India, has sparked off protests across the country. This article questions the so-called benefits of GM crops and highlights some major concerns. These include: inadequately addressed health and environmental risks, inadequate safety guidelines, a lack of transparency in sharing test data, the implications to seed sovereignty of farmers and the lack of informed choice for consumers. Some concerns about field testing by Mahyco, the developer of Bt-brinjal, and the process of evaluation by GEAC remain unresolved. With inadequate information about the crop's long-term safety, a precautionary approach is advocated before national policy allows commercial release of the seeds. A fair process is also needed in the public consultations being proposed by the minister of state for environment and forests. In addition to issues of procedural justice, a basic ethical question remains: do humans have a right to dominate the land and make expendable those creatures that they deem "undesirable"?

On October 15, 2009, the Genetic Engineering Approval Committee (GEAC) of the ministry of environment, the regulatory body for approving genetically modified crops (GM crops) in India, approved Bt brinjal, the first GM crop for human consumption in India, for commercial use (1,2). The approval came following the review of reports submitted by the Maharashstra Hybrid Seeds Company Limited (Mahyco), the Indian subsidiary of the US-based company Monsanto, that uses biotechnology to produce high yielding, pest resistant crops. The Tamil Nadu Agriculture University and the University of Agricultural Sciences, Dharwad, were partners of Mahyco in the development of Bt brinjal.

Bt Brinjal is a genetically modified plant in which a gene from the soil bacterium bacillus thuringensis is inserted into the genome of the brinjal, which can then produce a protein, Cry1Ac. This protein behaves as a toxin against the shoot and fruit borer (SFB), a pest that commonly affects brinjal. The gene modification also includes the addition of two antibiotic resistance marker genes.

Some media reports have been upbeat about the GEAC's approval (3), but the decision also sparked off protests. Environmental and health concerns were cited that extend to other GM crops in the pipeline like GM tomatoes, GM potatoes, GM cabbage, etc. Doubts have been raised about the science used in the technology as well as the interpretation of biosafety tests. The GEAC's decision needs to be ratified by the minister of state for environment and forests, Jairam Ramesh, before it becomes policy. Mr Ramesh announced that a series of consultations with scientists, agricultural experts, farmers' organisations, consumer groups and non-governmental organisations would be held in January and February 2010 before a final decision is taken in March 2010 (4). It is unclear whether healthcare professionals will also have a voice in these consultations.

The ethics of gene manipulations in the animal and human reproductive sciences, their clinical applications, and the impact on people's aspirations and life choices have been debated extensively by the healthcare professions. Genetic interventions in the food that we eat also affect our health, aspirations and life choices. As a healthcare professional concerned with bioethics, I decided to explore this controversy. Numerous and diverse issues emerged as I explored.

Why GM foods?

GM foods have been projected as a solution to world hunger, crop failures and farmer suicides. GM foods are promoted with the claim that they increase yields and reduce pesticide use, which benefits farmers, consumers and the environment (5).

Indeed, many studies demonstrate that GM crops like Bt maize and Bt cotton produce higher yields (6,7). However, it has been argued that such claims are blown out of proportion as the Bt toxin is basically an insecticide, and insecticides cannot increase yields, only reduce losses. It has also been argued that farmers have shown equal or greater yields with high-yielding native (non-GM) seeds and a careful planning of the season and location for planting (8). GM crops cannot even claim to address world hunger, which is due not to a lack of food, but to the fact that the poor do not have buying power. Finally, US studies indicate that pesticide consumption is low only in the first three years, after which its use has actually increased by about 4.1% in farms with GE varieties (9,10).

What are the concerns about GM food?

A number of concerns regarding GM foods have been inadequately addressed: the risk that they pose to people's health and the environment, the inadequate guidelines for assessing safety, the lack of transparency in sharing data related to safety testing, the implications for farmers' seed sovereignty, and the lack of informed choice for consumers.

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. Others may come as a complete surprise (11). It is worrisome that Mahyco has overlooked public communication about the potential risks in this technology.

Risks to health and the environment

Mahyco plans to extend Bt brinjal to nearly 50% of the acreage under brinjal cultivation in India (5). Environmental activists and farmers are concerned that gene migration can result in contamination of other crops; resistance can develop to the Bt toxin, which would result in an increased use of pesticides; soil may get contaminated with this increased pesticide use, and weeds resistant to the Bt toxin may emerge (12). Since 2002, three public interest litigations have been filed seeking a moratorium on GM crops (13). Mahyco's strategies for resistance management, submitted to the GEAC, are vague and not reassuring (14).

The gene transfer in Bt brinjal involves two antibiotic resistance marker genes for resistance to Kanamycin and Streptomycin. These are important drugs among the very few that we have in our armamentarium against tuberculosis. Mahyco states that these genes need a bacterial promoter for their expression, which would not be present in Bt brinjal (13). However there is a possibility that these genes can spread to other pathogenic bacteria by horizontal gene transfer and become active (15,16).

Some media reports record allergic symptoms and toxic reactions in both humans and animals after exposure to Bt cotton (17,18). Laboratory studies also show that the Bt protein has immunogenic and adjuvant capacities (19).

The testing requirements for GM crops are more lax than those for drugs. Drug trials are conducted in five stages, with the first stage, known as pre-clinical studies, involving only animals. Safety and efficacy issues in humans are addressed in the remaining phases (20). Government guidelines (21) for research in transgenic seeds or plants only require toxicity (with testing periods of 14 to 90 days) and allergenicity tests (with testing periods of 14-37 days).

It is surprising that regulations for a product meant predominantly for human consumption do not insist on human trials. Though the guidelines state that information related to toxicity and allergenicity to both humans and animals must be generated by the developer (18), Mahyco's toxicology studies have been performed only on animals and are therefore equivalent only to the pre-clinical studies that are prescribed for drug trials. Save a test that demonstrates that the toxin is undetectable within one minute of cooking, there are no other tests that demonstrate the safety of Bt brinjal for human consumption. It must be noted that Bt tomatoes and Bt cabbage (currently under development) would often be eaten raw. It is estimated that a kilogramme of Bt brinjal would contain 5-47 mg of the toxin, 100 times the minimum inhibitory concentration (MIC95) for the pest larvae (13).

The safety assessments done so far cannot exclude the possibility that humans may develop resistance to antibiotics, allergies or biochemical abnormalities due to the toxin. A number of reputed scientists have expressed concerns about GM foods (22). Jeffrey M Smith's *Genetic Roulette* (23) has a long, fully referenced list of the health risks of genetically engineered foods.

Was there research misconduct?

Some science organisations have alleged that appraisals of the Mahyco-Mosanto safety dossiers by independent scientists indicate that there has been incomplete disclosure regarding the bio-safety test results (24, 25). A French scientist, Gilles-Eric Seralini of the Committee for Independent Research and Information on Genetic Engineering, reviewed the safety dossiers. He discovered that safety tests found significant differences between GM and non-GM brinjal. But these differences were deemed biologically irrelevant and not investigated further. Seralini has also stated that some of the testing protocols are inadequate or invalid (22).

Was there conflict of interest?

Several NGOs had opposed the GEAC decision, in 2006, to appoint Deepak Pental, vice-chancellor of Delhi University, as chairperson of the 13-member expert committee on Bt brinjal (26). He was a known promoter of GM crops, he was working on GM mustard and his university was undertaking the same system of biosafety testing followed for Bt brinjal; the committee's recommendations would have a bearing on his own project. Also, at least three other members of the committee were actively involved in testing and developing other GM crops or were associated with biotech companies (27, 28). These commercial interests may have compromised the approval process.

A second expert committee (EC II) was constituted by the GEAC in January 2009 and submitted its report to GEAC on October 8, 2009 (29). The GEAC's approval took only six days and was not unanimous. Three members are reported to have expressed concerns and did not want the approval to be passed (1). Pushpa Bhargava, the only independent expert on the GEAC, a special invitee due to a Supreme Court ruling, is reported to have said that the safety assessment was not complete and noted that the regulators had not asked for an independent validation of any of the test reports submitted by Mahyco. However, his views were not supported by the GEAC.

Implications for farmers' seed sovereignty

Bt brinjal was developed by transforming the brinjal proprietary line of Mahyco, which will therefore own all Bt brinjal seeds. The company is awaiting a patent for its technology (5). Seeds for GM crops have to be bought from Mahyco and their franchisees, at the price set by them, which is a threat to the seed sovereignty of Indian farmers. The high seed cost will surely outweigh any advantage of reduced pesticide use. Farmers in Andhra Pradesh have already protested against

the exorbitantly high price levied for Bt cotton seeds (30) -- Rs 1,800-2,000 for 450 gm of Bt seeds, compared to Rs 450 for non Bt hybrid seeds. This amount includes Rs 1,200 as royalty to Monsanto. This is a major concern, given the credit constraints of Indian farmers.

Bt cotton hybrids require more water than the traditional varieties (31). In a predominantly rain-fed agrarian economy, high water requirements may destroy many GM crops as well as deplete already scarce ground water sources.

Implications for people's informed choices

Currently, there are no procedures to ensure that GM foods are labeled as such. When these foods are put on the market, people who would like to avoid GM food cannot exercise their informed choice.

Is there a need for precaution?

Genetic technology in the food industry has uncovered many exciting possibilities, but we must ensure that they are indeed safe and will not spring any surprises in future. We must pay heed to past lessons. DDT pesticide, promising in its early days, is now viewed as a major environmental pollutant and the UN is now considering banning it (32). The much hailed Green Revolution has caused irreparable damage in some regions (12). Since GM seeds will be released widely for agriculture, it is important to consider their effects on the integrity of complicated ecosystems and delicate biospheres. It may actually be impossible to reverse the changes that will occur in the environment.

India is a party to the Convention of Biological diversity (33) and the Cartagena Protocol on Biosafety (34). The Protocol is based on the Precautionary Principle which states that "When an activity raises threats of harm to human health or environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." The Protocol also states: "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;". The brinjal is an indigenous Indian crop with maximum genetic diversity. The Cartagena Protocol calls for extreme caution in introducing GM crops to countries which are the centres of origin for the non-GM varieties of those crops. In view of the seemingly irreconcilable concerns about the biosafety of Bt brinjal, would there not be justification to plead for a more precautionary approach?

In addition to concerns about safety, there is a basic ethical issue here. Do humans have a right to dominate the land and make creatures that they deem "undesirable" expendable? Is an industrial, commercial and profit-driven civilisation our goal?

The Bt brinjal controversy has elicited a very polarised and emotional debate between those for and those against the technology. Jairam Ramesh has an important responsibility to ensure a fair process in the consultations, including issuing advertisements, making documents available to the public for commenting and holding hearings in an empowering spirit. Civil society organisations too have an important responsibility to participate actively in the consultations and ensure that India's policy on Bt brinjal encompasses economic concerns, environmental health, people's health and choices.

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Was the Gadchiroli trial ethical? Response from the principal investigator

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In 2007, Oxford University Press published a book titled *Ethical issues in international biomedical research: a casebook* edited by James Lavery and others (1). One of the case studies presented by the editors and discussed by two discussants, Zulfiqar Bhutta and Marcia Angell, is titled 'Evaluating home-based treatment strategies for neonatal sepsis in India'. This case study is about the field trial of home-based neonatal care (HBNC) conducted in Gadchiroli, India by us (2). Earlier, Prof Anthony Costello from the Institute of Child Health, London (3) and now Sadath Sayeed from Boston (4) have put forward some facts and arguments about the ethics of the Gadchiroli trial. As the principal investigator of that field trial, I wish to add a few things.

1. In 1993, when we started this trial of HBNC, newborn mortality in developing countries was perceived by global policymakers and international organisations as a hopeless case for which not much could be done. For ethical consolation, most standard guidelines on the care of neonates in the community added the sentence: "If a neonate is sick, immediately hospitalise." Usually nothing more was offered to sick neonates. Because hospitals were neither accessible nor affordable, this advice practically meant: "Let them die." Four million neonates thus died every year, mostly in developing countries, the majority of them without receiving any medical care.

When we realised this cruel reality we were baffled but also compelled to do something for these millions of unreached, uncared for vulnerable neonates. There was little precedent to guide us. The challenge was daunting because standard medical advice was a joke in this situation but anything different would require taking an unchartered, risky path. The choice before us was either let four million neonates continue to die silently, every year, or take a risky path.

2. In 1993, our organisation SEARCH in Gadchiroli district had an ongoing child health programme area and also a non-programme area where only demographic surveillance was