GENETICALLY MODIFIED FOOD AND REGULATORY REGIME IN INDIA

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Freedom from hunger is one of the essential entitlements that have engaged the attention of the World Community at large[1]. The global demand for food is increasing because of the burgeoning world population and decreasing arable land, making it necessary to adhere to various methods for increasing quality and quantity of food supply. States have been pressurised into adopting measures to improve the production, conservation and distribution of food. Not only that, but also to disseminate information about nutrition and to structure the agrarian system to make the best use of natural resources.

Beginning with Louis Pasteur, work with wine, modern food, science and technology has made tremendous contribution to the safety and availability of food[2]. However recent development in the field while offering to extend this progress have posed concern about safety of these technology. Modern technology involving the use of DNA technology has emerged as powerful tool for improving both the quality and quantity of food supply and at the same time has evoked controversial debates relating to the potential impact on human health, environmental risks and also trade related issues[3].

Genetic modification is a special set of technologies that alter the genetic make up of such living organism as animals, plants or bacteria. Biotechnology, a more general term, refers to using living organisms or their components such as enzymes to make products that include tonic, cheese, beer and yogurt. Combining genes from different organisms is known as recombinant DNA technology and the resulting organism is said to be genetically modified, genetically engineered or transgenic. Genetically modified products (current or in the pipeline) include medicine, vaccine, foods or food ingredients, feeds and fibers[4].

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1. The idea of food entitlement is an ancient one. Confucius stated that feeding the people was the primary obligation of the State. The Old Testament prescribed detailed laws, which Jews were bound to follow, which provided for the poor and hungry to have access to productive land or food growing on the land of others.
2. www.who.int
3. Opponents of bio-technology are skeptical about the role of bio-technology in increasing the food security; they point to the threats that it poses to sustainable development to agricultural and environmental bio-diversity and to public health, they counsel caution about the not yet well known risks of gene technology. Floma Macmillan, WTO and Environment, Sweet and Maxwell, London, 2007.
4. It allows selected individual genes to be transferred from one organisms to another and also between non-related species.

Several genetically modified foods and products have entered the market in the last few decades. These include new protein sources from bacteria, filamentous fungi and yeasts and genetically manipulated plants and animals. The most controversial gene manipulation till date, perhaps has been the insertion of BT (Bacillus Thurungienis), which has entered more than 400 foodstuffs mainly soya-bean and of course cotton[5]. Bt[6] is the most effective in managing insects that are very hard to control for farmers producing cotton. The genetically modified Bt contains the insectidal gene of Bt, that itself makes toxin necessary for protection against pests. In short, it can be said that the plant itself becomes a pesticide and this is where the controversy emnates.

GM foods are developed and marketed because there is some perceived advantage either to the producer or consumer of these foods. The mutual objective for developing plant based on genetically modified organism was to improve crop protection by making them resistant to pests, herbicide, drought etc. For example, Bt crystal protein has been transferred into corn enabling the corn to produce its own pesticides against insects such as European corn borer[7]. Similarly, a plant is modified for herbicide tolerance by wherein the virus resistance is achieved through introduction of a gene from a bacteria, conveying resistance to some herbicide. Likewise plants are developed in a manner to resist disease, tolerate cold and drought, tolerance of salinity etc. Furthermore, plant modifications have also aimed at increasing nutritional levels. For example, the researchers at Swiss Federal Institute of Technology for Plant Science have created a strain of 'golden' rice containing an unusually high content of beta carotene (Vitamin A) [8]. Researchers are also working to develop edible vaccine and medicine, which would be easier to store, ship and administer, as compared to the conventional medicine/vaccine, which are often costly to produce and they require special storage[9].

Finally the food is much tastier and also of very good quality. Thus we can see that genetically modified foods definitely have a potential to change the future by making the developing nations in particular more self-sufficient, by

5. Shwetha Gupta, 'Genetically Modified Crops: a Question or Solution', *Amity Law Review*, Vol.5, Part I, January-June 2004, p.113.
6. It is common soil bacterium - a natural resource that has evolved over millennia, whose spray is one of the most important biological pest control techniques in use worldwide.
7. http//.www.csa.com
8. *Ibid.*
9. In 2003, about 167 million acres (67.7 million hectares) grown by 7 million farmers in 18 countries were planted with transgenic crops, the principal ones being herbicide and insecticide resistant soyabeans, corn, cotton, canola. Other crops grown commercially or field tested are sweet potato; resistant to a virus and could decimate most of the African harvest, rice with increased irons and vitamins that may alleviate chronic malnutrition in Asian countries and variety of plants able to survive weather extremes.

increasing the food security for the growing population.

Though there are several positive points to argue, critics have put forward several issues of concern, which need to be studied and assessed. This food revolution has instilled a fear of corporate control over agriculture leading to domination of world food production by a few companies[10]. This can in turn lead to increasing dependence of developing nation on industrialized nations who are more technologically advanced therefore more equipped in pioneering the production of genetically modified food. But the most serious allegation against genetic modification put forward by the critics is that it is destructive to human health and environment[11].

Hence it is necessary to have specific assessment to evaluate the potential risks to human health and environment unlike with traditional foods. The safety assessment of GM foods generally investigates direct health effect (toxicity). Tendency to provoke allergic reactions (allergenicity), specific components said to have nutritional or toxic properties, the stability of inserted genes, nutritional effects associated with genetic modifications and an unintended effect which could result from gene insertion[12]. However, four main issues currently debated as potential risks to health can be submitted as tendencies to promote newer toxicants, allergic reactions, gene transfer and out-crossing.

Genetic Engineering has the potential to alter such constituents or produce newer toxicants Crops developed for pest resistance and herbicide resistance are particularly focussed for toxicity concerns. The case of GM potato experiencing 'Galanthus Nivalis" lectin gene for insecticidal property is an example of the potential of GM foods to cause toxicity[13]. In a group of rats fed with GM potato, damage to immune system and stunted growth was observed[14].

While traditionally developed foods are not generally tested for allergencity, protocols for tests for GM food have been evaluated by FAO and WHO. Crops modified for insect resistance have shown to have the potential to allergic responses. This was highlighted in the recent findings of Starlink variety of GM maize, which has been shown to possess allergic properties in the food chains

10. *Supra n.*5.
11. The most important difference between genetic modification and older green revolution technologies is that the negative effect of the latter though serious can be reversed. The pollution caused by GM technologies is essentially irreversible.
12. *Supra n.*2.
13. Indian Council for Medical Research, Regulatory regiment for GM foods: the way ahead, April 2004 – at http //www.tccouncil.org
14. A 2005 study found that GM pea which is under development, caused severe immune responses in mice. In another study reported, GM maize fed rats developed major lesions in kidney and liver.

in USA, Europe and Japan[15]. The allergencity potential of GM food has often been difficult to establish with existing methods as the trangenes transferred are frequently from sources not eaten before, many have unknown allergencity or there may be a potential for genetic modification process to result in the increase of allergies already present in food[16].

Gene transfer from GM foods to cells of the body or to bacteria in the gastrointestinal tract could cause concern if the transferred genetic material adversity affects human health. This is particularly relevant if antibiotic resistance genes used in creating GMOs were to be transferred[17].

Outcrossing is the movement of genes from GM plants to conventional crops or related species in the wild (referred to as 'out-crossing') as well as mixing of crops derived from conventional seeds with those grown using GM crops may have an indirect effect on food safety or food security. This risk is real as was shown in traces of a maize type, which was only approved for feed use appeared in maize production for human consumption in the USA[18].

The assessment of risk to environment covers two aspects, that is the GMO concerned and the potential receiving environment. The assessment process includes the evaluation of the characteristic of the GMO and its effect and stability in the environment combined with ecological characteristics of the environment in which the introduction takes place. Issues of concern includes the capacity of the GMO to escape and potentially introduce the engineered genes into the wild population, the persistence of genes after the GMO has been harvested, the susceptibility of non-target organism (insects which are not pests) to the gene product, the stability of the gene, the reduction in the spectrum of other plants including the loss of biodiversity, the increased use of chemicals in agriculture[19]. Further, different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should b e assessed on case-by- case basis and it is not possible to make general statements on the safety of all GM foods.

On ethical grounds too, GM crops have led to some controversies such as violation of natural organisms intrinsic values, tampering with nature by mixing genes among species and objection to consuming animal genes in plants and

15. Supra n.13.
16. After GM Soya was introduced in UK cases of allergies went up. It was also suggested that insertion of genes that code for novel proteins, not normally present in traditional foods may result in increased allergic reaction in some consumers. See Kamala Krishnaswamy – GM Foods – Potential benefits and possible hazards, July 2001 at http://nutritionfoundationofindia.res.in
17. Supra n.2
18. Ibid.
19. The environment safety aspects of GM crops vary considerably according to local conditions.

vice versa[20].

Therefore, it becomes all the more important for countries to map out a thorough safety assessment of GM foods before they are made available for consumption. The Codex Alimientaries Commission, an intergovernmental organization, jointly set up by the FAO and WHO, is the main international body responsible for developing international food standards[21]. Codex standards are not mandatory and cannot affect national legislation of foodstuffs[22] but nevertheless they are considered to b e prime authorities in setting standard which nations are persuaded to follow[23]. Other than the Commission, safety assessment of GM food has been addressed by several other international organizations namely the Food and Agricultural Organization (FAO), World Health Organization (WHO) and the Organization of Economic Co-operation and Development (OECD).

GM foods are subjected to an array of analytical tests for food safety evaluation like chemical analysis, allergenity tests and also evaluation of nutrition composition. The fundamental approach to assessing the safety of GM ingredient is based on the principle of substantial equivalence (SE) [24]. SE is concept formulated from the OECD guidelines and is a comparative approach where a comparison of various agronomic, biochemical, chemical and nutritional parameters of the GM food, relative to the existing food or food component is used as a method of assessing safety/quality[25]. If the food is substantially equivalent in composition and physical characteristics, to its conventional counterpart, it is deemed safe.

Though regulation of GM food is a priority today, there is a vast gulf in the manner of regulation. In some countries, GM foods are not regulated. Around 130 or more countries have no regulation[26], while 30-40 countries including India have put into place bio-safety legislation and regulatory institutions to implement them, both for research and trade of GM foods and food ingredients derived from them.

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20. *Supra n.*5.
21. *Ibid.*
22. Butterworth Law of Food and Drugs, Lexis – Nexis, UK, Issue 77, August 2004, A.22.
23. They are however influential in that products complying with codex standard are either 'accepted' in member countries or are given 'free entry' to the markets of these countries. In a review carried out in late 1986, it was found that there had been 857 specific responses to codex standards of which 70% were 'acceptances' and 30% were 'free entry' notification. In some countries, codex Standard are accepted as basis of legislation and in many other they are influential in determining the final form of such legislation.
24. *Supra n.*16.
25. FAO bio-technology and food safety. FAO food and nutrition paper 61, 1996.
26. *Supra n.*16.

Several ministries and departments are involved in India's program of food quality and safety and hence each one of them has a role to play in the activities related to GM foods in India.

The Ministry of Environment and Forests notified the rules and procedures for the manufacture, import, use, research and release of genetically modified organism (GMO) as well as products made by the use of such organisms, on Decemberr 5th, 1989, under the Environmental Protection Act 1986. Two main agencies responsible for implementation of rules are the Ministry of Environment and Forests (MOEF) and Department of Biotechnology (DBT). There are six competent Committees, which have been set up as per the rules – Recombinant DNA Advisory Committee (RDAC); Review Committee on Genetic Manipulation (RCGM); Genetic Engineering Approval Committee (GEAC); Institutional Bio-safety Committee (IBSC); State Bio-safety Co-ordination Committee (SBCC); District Level Committee (DLC) [27]. As per the provisions of S.11 of Rules 1989, "Food stuffs, ingredients in food stuffs and additions including processing aids containing or consisting of genetically engineered organism or cells shall not be produced, sold, imported or used except with the approval of GEAC."[28].

The Department of Biotechnology holds the Secretariat of Review Committee on genetic modification that gives approval for research and small scale field trials involving GMOs and products thereof. It also interacts with the Institutional Bio-safety Committee (IBSCs), which are set up in all organizations undertaking activities involving GMOs. The Department of Biotechnology had formulated recombinant DNA guidelines in 1990. These guidelines were further revised in 1994 to cover research and development activities involving GMOs, transgeneric crops, large scale production and deliberate release of GMOs, plants, animals and products into environment, shipment and importation of GMOs for laboratory research[29].

Department of Health in the Ministry of Health and Family Welfare is responsible for implementation of Prevention of Food Adulteration Act 1954,

27. Dr. Vibha Ahuja and Dr. Geetha Jotwani, The regulation of Genetically modified organisms in India, at http://www.agbios.org.
28. The new import policy of GMOs/LMOs issued by DFGT – The Ministry of Commerce through DGFT vide notification No.2 (RE 2006)/2004-2009 at 7-4-2006, mandates prior approval of GEAC for all GM products including food items.
29. The guidelines employ the concept of physical and biological containment and principle of good laboratory practices. For containment facilities and bio-safety practices, recommendation in the WHO laboratory safety manual on genetic engineering techniques including microorganisms of different risk groups have been incorporated therein. For release to the environment too, the guidelines specify appropriate containment facilities depending on the type of organisms handled and potential risks involved.

which was enacted with the objective of assessing the quality and safety of food as well as to encourage fair trade practices[30]. On March 10th 2006, the MOH amended the Act rules necessitating compulsory labeling of GM food. The amendment stipulates that no person shall except with approval of and subject to condition that may be imposed by GEAC constituted under Environment Protection Act 1986, manufacture, import, transport, store, distribute or sell raw or processed food, food additives or any food product that may contain GM materials in the country[31].

The Indian Council of Medical Research acts as an advisory body to the Ministry of Health and Family Welfare on various issues including GM foods. Further crucial roles are also played by the Indian Council of Agricultural Research and Ministry of Agriculture particularly in the approval of GM crops as per Seed Policy 2002.

On April 7th 2006, Government of India amended the Foreign Trade (Development and Regulation) Act of 1992 governing rules on import of GM crops. As per the amendment, the imports of GMO for food, feed or processing, industrial processing, research and development for commercialization or environmental release would be allowed only with approval of GEAC. At the same time, all shipments including products containing GMOs have to carry a declaration stating that the product is genetically modified. If the shipment does not contain traces of GM material, the importer is liable for penal action under this Act[32].

In actuality to protect the interest of consumer and also for them to exercise their choice, the labeling should be based on precautionary approach with zero tolerance for any GM contamination. But it is a disappointment to see that the Ministry of Health's amendment requires producer/importer to merely carry a label that would state that the product 'may contain' GM material. Instead of rigorous bio-safety tests before allowing the import, the MOH is merely relying on the safety information provided by the importer[33].

Moreover, facilities present within the country for testing products for presence of GM are grossly inadequate. There is no laboratory in the country, which undertook such testing. Moreover testing protocols have still to be developed. Until such system is put in place it is obvious that the legislation in its

30. Provisions apply to imported food as well as food produced in India.
31. The US claims that the 1989 rules under the EPA are vague and broader than any other existing biotechnology regulation across the world, with regard to import of GM products – they have questioned the rationale of seeking information on every shipment of the same product to be submitted in GEAC.
32. The changed rule came into effect on July 8th 2006.
33. *Supra n.*2

present form is intended to legalize the importance of untested GM food in the country.

Methodology used for food and feed safety tests must be made known to be public and also the laboratories where the safety tests were conducted. All decisions regarding GM crop and food must be taken in accordance with the Cartegena Protocol on Bio-safety.

A competent, transparent and independent regulatory process with more participation from public/civil society to oversee all aspects of GM crops and food must be put in force. At present, there seems to be a few shortfalls, inspite of the elaborate regulatory system in India. For example, soyabean oil imports have been going on for long years primarily to bridge the domestic demand-supply gap of edible oil. It is well known that soyabean produced in major origins such as the US, Brazil and Argentina are laregely genetically modified and these countries, neither segregated genetically modified and non genetically modified material, nor do they follow any labeling policy[34].

GM foods are of much significance for a child's health particularly when they become a part of supplementary feeding programmes. Foods distributed to children as part of the Government supplementary feeding programmes may contain soyabean flour and maize flour as sources of protein and calories in the supplement. The replacement of these foods with GM soya and maize would require a very vigilant system of safety evaluation. In the Indian context wherein adequate testing facilities and monitory system do not exist as yet, such GM foods could escape detection.

All in all, there seems to be a lack of adequate standards for risk assessment. A dearth of skilled personnel and of course the infrastructure has made any kind of assessment mere perfunctory. Risk assessment incorporating the precautionary principle as contained in the Caragena Protocol and the Sanitary and Phytosanitary agreement must be instituted into the regulatory framework. Further, the principle of information exchange, informed consent and labeling as expressed in the Cartagena Protocol must be strictly adhered to.

As India joins other countries in the quest of new technological revolutions, they must be cautious of the potential risks that it may have to man and environment and take the necessary antidotes. Genetically modified food is perhaps here to stay and there is an urgent need to integrate all possible precautions to see that both man and his environment benefit from the progress made by development and research.

34. G. Chandrasekar. "Policy on import of GM foods flawed". The Hindu Business Line, 11th May 2006, at www.gene.ch.