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Genetically Modified Organisms and Food Safety Regulations: An Indian experience

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Abstract
Regulation of GM crops in Indian framework has been an issue of good debate in the recent past. This is accentuated by the fact that there are many genetically modified crops in the pipeline, waiting for approvals for various stages of trials like GM Potato, GM Mustard, GM Brinjal and GM Rice etc. At this juncture the key issue for consideration is that where the problem exists in the presence of multiple regulations related to the genetically modified organisms. Among the catena of laws the author aims to focus only upon the food safety aspect of the genetically modified organisms. The author presents an overview of food safety regulations in India to ensure fair use of genetic engineering in the era of commercialization. Further the relevant provisions have been analysed to find out the solution of the problem related to implementation of the said laws.

Keywords: *Genetically Modified Organisms, food safety, GM food, Regulation, Prevention of Food Adulteration Act, 1954, The Food Safety and Standards Act, 2006*

Introduction

To ignore the plight of starving people is as morally reprehensible as failing to save a child drowning in a pool because of the inconvenience of getting one's clothes wet (Clair & Manuel, 1992). Science and Technology has proved its worth to mankind at number of occasions and one of them is to promise the access to food for all. To ensure the same Genetically Modified Crops have been developed as a solution. However the solution also involves certain risks due to the release of Genetically Modified Crops for field-testing and commercialization. Concerns have been expressed about the potential risks associated with their impact to human health, environment and biological diversity as well. These apprehensions arise because genetic engineering crosses the species barrier as compared to classical selection techniques, thereby permitting the gene transfer among microorganisms, plants and animals. Although there is no evidence that any unique hazards exist in the development of GM, because of novel combinations of genes (Vibha & Gita). Further, the concerns in agriculture do not necessarily lie with the characteristics of the products rather with the way it is produced particularly in case of food crops. Any innovation in the process of production of crops poses multiple questions in the mind of consumers and food experts. Therefore bio-safety legislations and regulatory regimes have been put in place by many countries including India to address these concerns. The objective of the legal regime is to encourage research and trade related to the GM food and food ingredients derived from them within the framework of safety measures. It is the responsibility of the scientists, industry, and the government to assure the public for the safety of the novel food products.

General Overview of GMO Regulation

In India, genetically modified organisms and products are primarily governed under the Environment Protection Act, 1986 (EPA). The Central Government, exercising its powers under the Act, passed the 1989 "Rules for the manufacture, use, import, export and storage of Hazardous Micro-organisms, genetically engineered organisms or cells" (1989 Rules). As required by the 1989 Rules, Department of Biotechnology (DBT) also issued guidelines in 1990, which were further revised and expanded in 1994 and 1998 (DBT 1994, 1998). These rules and guidelines regulate the entire spectrum of activities relating to GMOs. They also regulate production facilities, like tanneries and distilleries as well as laboratory practices and containment facilities. It may be noted that the 1998 DBT guidelines call for demonstration that the transgenic plant "is both environmentally safe and economically viable".

The Genetic Engineering Approval Committee (GEAC) has been authorized as the inter-ministerial body under the Ministry of Environment and Forests to be the authority to permit any manufacture, use, import, export and storage of hazardous micro-organisms and genetically modified organisms or cells. In practice, it is the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology that is currently authorizing research up to limited field trials and also imports of GM material for research purposes. In addition to these rules, guidelines and specific formats are prescribed for the actual experimentation and release of genetically modified organisms and their import. Other then this under the Health Ministry, the Indian Council of Medical

Research (ICMR) had stated its own views on the regulatory regime and the way ahead for genetically modified foods in the country. The ICMR opines that the safety assessment of GM foods should be as per *Codex Alimentarius*.

Laws Relating to Food and Safety Regulation

This part of the paper will deal with the pre and post Food Safety and Standards Act, 2006 (hereinafter referred as FSSA) position of law governing to food and safety standards in India. The pre FSSA law majorly focuses on the PFA, 1954 and other related laws (See references). The post FSSA position deals with the provisions of Food Safety and Standards Act, 2006 and the procedure of regulating GM crops in India.

Pre FSSA Position (Prevention of Food Adulteration Act, 1954)

A comprehensive legislation called the Prevention of Food Adulteration Act (See references) has been enacted in 1954, which came into effect from June 1, 1955, with the objective of assuring the quality and safety of food as well as to encourage fair trade practices. The Act has been amended a number of times to make the provisions more practical and consumer-oriented. This Act is the basic statute intended to protect the consumer from the supply of adulterated food and it specifies food safety and quality standards for consumer protection. The definition of 'adulteration' includes the addition of cheaper or inferior substances to deceive the consumer and the presence of contaminants, which may make the food, unfit for human consumption. The objective of this legislation is, therefore, not only to ensure pure and wholesome food to the consumers, but also to prevent fraud or deception. It lays down that no person shall manufacture, sale, store, or distribute adulterated or misbranded food products not conforming to the standards laid down in the rules. The provisions apply to imported food as well as to food produced in India.

The responsibilities of the PFA cell in food control system are as follows:

1. Enhance the availability of safe and wholesome food.
2. Consumer protection from deception, fraud and food-borne diseases.
3. Risk analysis, risk management and risk communication.
4. Ensure safety of genetically modified food.
5. Enhance the involvement of NGOs and Home Science Institutes.
6. Educational authorities to ensure better consumer protection.
7. Promote a voluntary management system, the Code of Ethics, through principles of GMPs and the HACCP.

Regarding laboratory facilities under the PFA Act, there are approximately 80 food laboratories in the country undertaking the analysis of samples of food articles under the provisions of the PFA Act, out of which 13 are managed by local bodies (municipalities). These are known as Public Analyst Laboratories. In addition, there are four Central Food Laboratories notified under the PFA Act to carry out an analysis of appeal samples whenever the report of the public analyst is challenged in the court of law. These are situated in Kolkata, Ghaziabad, Mysore and Pune. These laboratories analyze the bulk of the samples under the PFA Act.
Regarding inspection and certification procedures for imported food, Section 5 of the PFA Act, 1954, prohibits the import of the food which is adulterated and the food which is misbranded or the food which contravenes any other provision of the PFA Act or any Rule. Section 6 of the Act is required to be followed essentially while importing or clearing the food products which include checking of the imported food products by the authorized officers. Section 6 of the PFA Act, 1954 authorizes the custom collector to check the imported food products. The authorized officer, on suspicion, may detain any imported food product. He may send the samples of the detained product to the Central Food Laboratory for analysis. Imported food is inspected at the ports of entry by personnel of the Collectorate of Customs. If necessary, samples are further tested in the laboratories designated/notified for this purpose by the Ministry of Health and Family Welfare to verify the compliance with the requirements stipulated under the PFA Act, 1954 and Rules.
With a view to streamline the checking of imported food products, the Government of India issues various instructions from time-to-time. Various departments of the Government of India, including Health, Revenue, Commerce and the Directorate General of Foreign Trade, have initiated several steps to streamline the checking of imported food. Regarding procedures for food export inspection and certification, the Export Inspection Council (EIC) of the Ministry of Commerce and Industry is the official government inspection body for certifying food products for export. It carries out the inspection of several food articles such as marine, milk products, meat, honey, poultry, Basmati rice, black pepper and cashew meant for export.

Post FSSA Position

The Food Safety and Standards Act, 2006

The Prevention of Food Adulteration Act (PFA), 1954 was regulating the labeling of GM foods before 2006 (PFA is replaced by Sec. 97 of FSSA) under the Ministry of Health & Family Welfare. Now the Food Safety and Standards Act, 2006 (FSSA) has replaced existing Acts or Orders related to various food sectors in the country. Therefore the food safety and standards are to be administered and monitored by Food Safety and Standards Authority of India. The Food Safety and Standards Act, 2006 (34 of 2006) was enacted by the Parliament with objective to consolidate the Laws relating to food and to establish Food Safety and Standards Authority of

India for laying down science based standards of articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto. The provisions related to the GM food and derivatives regulation of the new Act are discussed hereunder.

Provisions related to genetically modified organisms under the Act:

i. **Definition of Food (Sec. 3 (1) (j)):** "food" means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk), genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances.

ii. **Scientific Panels (Sec. 13):** (1) The Food Authority shall establish scientific panels, which shall consist of independent scientific experts.
(2) The Scientific Panel shall invite the relevant industry and consumer representatives in its deliberations.
(3) Without prejudice to the provisions of sub-section (1), the Food Authority may establish as many Scientific Panels as it considers necessary in addition to the Panels on:
(c) genetically modified organisms and foods;
(e) biological hazards;
(f) contaminants in the food chain;
(g) labeling; and
(h) method of sampling and analysis.

iii. **Genetically modified foods, organic foods, Functional foods, proprietary foods, etc. (Sec. 22):**
Save as otherwise provided under this Act and regulations made there under, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, neutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf. For the purposes of GMO regulation in this section Explanation (2), (3) and (4) are important. The Explanations are as follows:
Explanation(2) "genetically engineered or modified food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;
Explanation (3) "organic food" means food products that have been produced in accordance with specified organic production standards;
Explanation (4) "proprietary and novel food" means an article of food for which standards have not been specified but is not unsafe: Provided that such food does not contain any of the foods and ingredients prohibited under this Act and regulations made there under.

iv. **Packaging and labelling of foods (Sec. 23):**
(1) No person shall manufacture, distribute, sell or expose for sale or dispatch or deliver to any agent or broker for the purpose of sale, any packaged food products which are not marked and labeled in the manner as may be specified by regulations:
Provided that the labels shall not contain any statement, claim, design or device which is false or misleading in any particular concerning the food products contained in the package or concerning the quantity or the nutritive value implying medicinal or therapeutic claims or in relation to the place of origin of the said food products.
(2) Every food business operator shall ensure that the labelling and presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, does not mislead consumers.

v. **All imports of articles of food to be subject to this Act (Sec. 25)**:
(1) No person shall import into India -
(i) any unsafe or misbranded or sub-standard food or food containing extraneous matter;
(ii) any article of food for the import of which a license is required under any Act or rules or regulations, except in accordance with the conditions of the license; and
(iii) any article of food in contravention of any other provision of this Act or of any rule or regulation made there under or any other Act.

(2) The Central Government shall, while prohibiting, restricting or otherwise regulating import of article of food under the Foreign Trade (Development and Regulation) Act, 1992 (22 of 1992), follow the standards laid down by the Food Authority under the provisions of this Act and the Rules and regulations made there under.

vi. **Purchaser may have food analysed (Sec. 40)**: It enables the purchaser of any article of food to get analyzed such food from the Food Analyst after informing the food business operator at the time of purchase of his intention to have such article so analyzed.

The Act, *inter alia*, incorporates the salient provisions of the Prevention of Food Adulteration Act, 1954 and is based on international legislations, instrumentalities and Codex Alimentarius Commission which is related to food safety norms. So overall it may be said that the above said Act is contemporary, comprehensive and intends to ensure better consumer safety through Food Safety Management Systems and setting standards based on science and transparency as also to meet the dynamic requirements of Indian Food Trade Industry and International trade. It is noteworthy here that the GM Imports are regulated through the EPA Rules, labeling proposals as well as guidelines issued by the Commerce Ministry in 2006.

Procedure of Regulating GM Crops in India (As per Draft National Biotechnology Regulatory Authority Bill, 2008**):**
In India GM crops have to qualify five tier testing procedure before commercial cultivation, that is as following;

1. RCGM examines the application for testing of GM crops.
2. After clearance by RCGM, GEAC examines the application for field trial. If permission is granted, GEAC examines the field trials and decides whether a GM crop should be commercially cultivated or not.
3. After that MEC monitors the trials of small level and its report is presented to RCGM. It considers on bio-safety issues.
4. GEAC on the report of MEC grants permission for commercial production of that GM crop.
5. Central Agricultural Ministry after consulting the Seed Act, 2004 grants permission to the seed for sale in the market.

Conclusion

In a nutshell, the food safety regulations takes care of international practices and envisages an over-reaching policy framework to guide and regulate persons engaged in manufacture, marketing, processing, handling, transportation, import and sale of food. It can be said after examining the various laws that the promises by legislations and regulations are many and the problems are equally bothersome. Biotechnology is a major source of public power in modern society and raises important concerns regarding rights of use, right to information, control and participation in its use. Multiplicity of GM food laws, standard setting and enforcement agencies pervades different sectors of food, which creates confusion in the minds of consumers, traders, manufacturers and investors. Detailed provisions under various laws regarding admissibility and levels of food additives, contaminants etc. and other related requirements have varied standards under these laws. The standards are often rigid and non-responsive to scientific advancements and modernisation. In view of wide range of provisions their enforcement is very callous. So it is suggested that rather being so ambitious and theoretical the grass root implementation of the law is required. This will help to serve the ultimate ends of justice that is the food safety and standardisation.

References

Claire Andre & Manuel Velasquez, *World Hunger: A Moral Response*, Issues in Ethics - V. 5, N. 1 Spring 1992 available on https://www.scu.edu/ethics/publications/iie/v5n1/hunger.html visited on April 12, 2014
Dr. Vibha Ahuja and Dr. Geeta Jotwani, *The Regulation of Genetically Modified Organisms in India,* available on http://www.agbios.com/docroot/articles/05-265-003.pdf.
Draft National Biotechnology Regulatory Authority Bill, 2008
Rule 4(4), of Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms Genetically Engineered Organisms or Cells, 1989, notified under the EP Act, (1986) by Ministry of Environment & Forests.
The Act is now replaced by Food Safety and Standards Act, 2006 (FSSA)
The Prevention of Food Adulteration Act, 1954 is repealed by S. 97 of FSSA.
The Acts are: 1. The Prevention of Food Adulteration Act, 1954 (37 of 1954), 2. The Fruit Products Order, 1955, 3. The Meat Food Products Order, 1973, 4. The Vegetable Oil Products (Control) Order, 1947, 5. The Edible Oil Packaging (Regulation) Order, 1998, 6. The Solvent Extracted Oil. De oiled Meal, and Edible Flour (Control) Order, 1967, 7. The Milk and Milk Products Order, 1992, 8. Any other order issue under the Essential Commodities Act, 1955 (10 of 1955) relating to food.
Various food and safety laws viz.1. The Prevention of Food Adulteration Act, 1954 (PFA), 2. The Fruit Products Order, 1955, 3. The Meat Food Products Order, 1973, 4. The Vegetable Oil Products (Control) Order, 1947, 5. The Edible Oil Packaging (Regulation) Order, 1998, 6. The Solvent Extracted Oil. De oiled Meal, and Edible Flour (Control) Order, 1967, 7. The Milk and Milk Products Order, 1992, 8. Any other order issue under the Essential Commodities Act, 1955 (10 of 1955) relating to food.