Centre for Science and Environment

GENETICALLY MODIFIED PROCESSED FOODS IN INDIA

Need to Curb Illegal Sales in the Indian Market

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Executive summary

Foods produced from genetically modified organisms (GMOs) are referred to as genetically modified (GM) foods. The safety of GM foods has been a matter of concern. The Food Safety and Standards Authority of India (FSSAI) has not allowed GM foods in India so far.

To understand whether GM foods are available in the Indian market, the Pollution Monitoring Laboratory (PML) at the Centre for Science and Environment (CSE) tested 65 imported and domestically produced processed-food samples. Testing involved qualitatively screening for the presence of GM DNA (deoxyribonucleic acid) through the qPCR (quantitative polymerase chain reaction). The food samples were made from or likely to contain ingredients from soya, corn, rapeseed or cottonseed and were a mix of oils, packaged foods, infant foods and protein supplements.

Overall, 32 per cent of the food product samples tested were GM positive. Forty-six per cent of imported food products tested positive. These were made of or used soya, corn and rapeseed and were imported from Canada, the Netherlands, Thailand, the UAE, and the US. About 17 per cent of the samples manufactured in India tested positive. All of these were of cottonseed oil. Out of the 20 GM-positive packaged samples (excluding crude cottonseed oil), 13 did not mention use of GM ingredients on their labels. Some brands had claims on their labels suggesting that they had no GM ingredients but were found to be GM positive.

Fifty-six per cent of oil samples—including canola oil (rapeseed) imported from Canada and the UAE, and Indian cottonseed oil—tested positive. Twenty-five per cent of packaged food samples were positive. All of these were imported samples and most were corn-based from the US. Two infant food samples imported from the US and the Netherlands also tested GM positive.

CSE recommends that in the interest of public health and informed consumer choice, the FSSAI take the following necessary actions at the earliest:

- Identify all illegal GM foods, ensure that they are not available in the Indian market and take necessary legal action against concerned companies and traders.
- Set up a stringent system for approving domestically produced and imported GM food products based on safety assessments.
- Enact 'GM labelling laws with stringent exemption limit, clear symbol-based depiction of GM label and qualitative screening as an enforcement tool.
- Set up laboratories for testing GM foods.

Introduction

Genetically modified (GM) foods

Food produced from or using genetically modified organisms (GMOs) is referred to as GM food.[1] It could include processed foods such as oil used as a cooking medium or ready-to-eat snacks such as chips or breakfast cereal made from GM crops such as soya bean, corn, cottonseed, tomato and potato.

Genetically modified organisms

GMOs are defined as organisms (plants, animals or microorganisms) in which the genetic material (deoxyribonucleic acid or DNA) has been altered so that it does not occur naturally by mating and/or by natural recombination. They are produced as a result of genetic engineering technology, also known as 'modern biotechnology' or 'recombinant DNA technology', which allows the transfer of selected individual genes from one organism to another as well as between organisms of non-related species such as the transfer of genes from bacteria to a plant.[2]

GM food from GM crops

GM crops are developed and marketed because of certain perceived advantages to producers or consumers, including crop protection from pests or diseases, tolerance to herbicides or increased nutritional value. There are, however, uncertainties around these claimed benefits of GM crops/foods as well as their safety to the health of humans, animals and the environment.

Based on these concerns, the cultivation of GM crops and availability of GM foods is regulated across different parts of the world. GM corn, rapeseed, soya and cotton account for 99 per cent of the world's GM crop acres.

India has allowed commercial cultivation of only GM Bt (*Bacillus thuringiensis*) cotton since 2002 (see *Table 1: Common GM varieties globally marketed*).

Table 1: Common GM varieties globally marketed

GM crops used for GM foods	GM DNA	Claimed mode of action
Corn, soya, cotton	The insect-resistance gene from bacteria *Bacillus thuringiensis* (Bt) is transferred to the crop.	The Bt GM crop expresses the BT gene, which codes for Bt toxin protein. Insects that feed on Bt crop ingest Bt protein, which attacks their gut cells and kills them.
Corn, soya, cotton, rapeseed (canola)	The herbicide-tolerant (HT) gene, a modified form of the EPSPS* gene sourced from plants, is inserted in to desired crop.	Herbicides target the EPSPS protein produced by plants for their survival. The HT GM crop expresses the HT gene that codes for a modified EPSPS protein, which is not degraded by herbicides (glyphosate and glufosinate).

* 5-enolpyruvylshikimate-3-phosphate synthase

CSE STUDY: DETECTION OF GENETICALLY MODIFIED PROCESSED FOODS IN INDIA

Objective

To detect the presence of GM processed foods available in the Indian market.

Samples tested

Food products made from or likely to contain ingredients from soya, corn, rapeseed or cottonseed were tested as GM variants of these crops are cultivated in different parts of the world. The products were randomly purchased from retail outlets in Delhi NCR, Gujarat and Punjab. All the samples tested were of processed foods except for one of crude cottonseed oil.

A total of 65 samples were tested out of which 30 were manufactured domestically in India and 35 imported from countries such as Australia, Canada, Ireland, Mexico, Malaysia, the Netherlands, Spain, Singapore, Thailand, the UAE and the US. Collectively, these food products could be segregated into four broad categories and several subcategories (see *Table 2: Food products tested for presence of GM markers*).

Table 2: Food products tested for presence of GM markers

Food product category	Domestic or imported	Subcategories
Oils—16	Domestic—9 Imported—7	Canola oil—7, soya bean oil—3, cottonseed oil—4, crude cottonseed oil—1, corn rice bran oil—1
Packaged food—39	Domestic—18 Imported—21	Ready-to-cook categories—8: Soya chunks— 4, soya sauces—3, breakfast cereals—5, sweet corn soups—3, sweet corn (kernels, frozen)—6, tofu—1, corn-based syrups—3, popcorn—2 Ready-to-eat categories—9: Ready-to-eat popcorn—1, potato chips—2, tortilla chips—1, soya milk—1, peanut butter—1, corn coating on meat—1, confectionery (pop tarts)—1, namkeen and snacks—3, croutons toast bread—1
Infant foods—8	Domestic—2 Imported—6	Soy-based formulas—3, hypoallergenic infant formula—2, other infant formulas—3
Protein supplements—2	Domestic—1 Imported—1	Protein supplement for adults—1, soya bean-based nutritional beverage mix—1

Methodology

Living organisms—plants, animals and humans—contain DNA as their genetic material. Non-GM organisms—unlike GMOs—contain foreign DNA elements because their DNA is altered by genetic engineering. It is thus possible to differentiate non-GM and GMOs on the basis of foreign DNA elements.

This study identified GM ingredients in food samples by testing them for the presence of three different foreign DNA elements, i.e. 35S promoter (sequence from cauliflower mosaic virus), FMV promoter (sequence from figwort mosaic virus) and NOS terminator (sequence from *Agrobacterium tumiefaciens*),

which would only be present if a sample contained GM ingredients. Hence, these are considered GM markers. A combination of a promoter and terminator GM marker is present in over 95 per cent of currently available GM crops.[3]

In the case of solid samples such as packaged foods, infant foods and protein supplements, 2 grams of sample was used to extract the DNA using a kit and as per manufacturer instructions (DNeasy mericon Food Kit [Qiagen, USA]). For liquid samples such as oil, soya milk and corn syrup, 300 millilitres of sample was concentrated by centrifugation and the DNA isolated from the pellet. Good-quality DNA isolated from food samples was subjected to qPCR (quantitative polymerase chain reaction) analysis (SureFood® GMO SCREEN 4plex detection kit (CONGEN Biotechnologie GmbH) purchased from R-Biopharm AG, Germany—compliant with German Food Law § 64 for detecting GM DNA sequences), which enabled researchers to amplify these specific GM markers to detect their presence. Samples were run in triplicate and the value of mean Ct (threshold cycle, which indicates the presence of GM markers) was used to identify GM-positive samples. A sample was considered positive when it showed a detectable Ct value for a combination of a promoter and terminator GM marker.

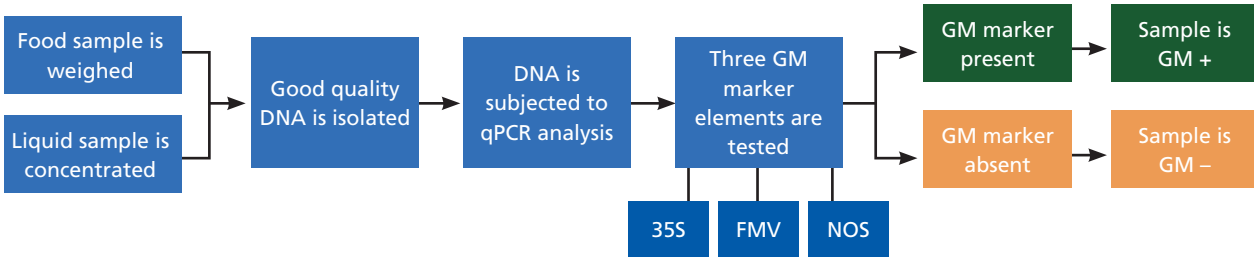
In addition, samples of cotton leaf and commercially available cottonseeds (Super-931, Bollgard II, Monsanto) were used as positive controls and sterile molecular grade water was used as a negative control in each qPCR run. The results from control samples validated the methodology and test results of the study (see *Figure 1: Methodology for testing GM markers in food samples*).

Results

Overall, 32 per cent (21/65) food product samples tested were GM positive (see *Table 3: GM-positive food product samples*).

- About 46 per cent (16/35) of imported food products were GM positive. The food products were imported from Canada, the Netherlands, Thailand, the UAE, and the US. About 17 per cent (5/30) of the samples manufactured in India were positive.
- GM-positive imported food products were based on or used soy, corn and rapeseed. Positive samples manufactured domestically were made from cottonseed, i.e. cottonseed oil.
- Out of the 20 GM-positive packaged samples (excluding crude cottonseed oil), 13 did not mention use of GM ingredients on their labels.
- Three out of five brands that had claims on their labels suggesting no use of GM ingredients were found GM positive. These were Candrop canola oil imported from Canada, Mori-Nu tofu imported from the US and PromPlus sweet whole kernel corn from Thailand.
- Labels of only five samples suggested that GM ingredients were used. Three declared 'partially produced with genetic engineering' and two mentioned

Figure 1: Methodology for testing GM markers in food samples



'produced with genetic engineering'.
- All product categories—except protein supplements, in which only two samples were checked—were GM positive.

Oils: 56 per cent (9/16) of oil samples tested were GM positive.
- Four out of seven tested canola oil (rapeseed) samples were positive. These were imported from Canada (Canola, Jivo) and the UAE (Hudson, Farell).
- All five samples of cottonseed oil from India were GM positive. The brands included Tirupati, Ankur, Ginni and Vimal. The sole sample of crude cottonseed oil was also positive.
- No GM-positive packaged oil sample mentioned GM ingredients on its label.
- Samples of soya bean oil and blended oil (corn and rice bran) that were sourced from India were not found to be GM positive.

Packaged foods: 25 per cent (10/39) of packaged food samples tested GM positive.
- About 50 per cent (10/21) of the imported samples tested were positive. These included two ready-to-eat and eight ready-to-cook samples. Most of these positive samples were corn based.
- Nine out of 10 of these brands were imported from the US, including Kellogg's Froot Loops cereal, American Garden popcorn, Mrs. Cubbison's Croutons Toast Bread, Trix Corn Puffs, Mori-Nu tofu, Bugles corn snacks, and Karo, American Garden and Aunt Jemima corn-based syrups. The remaining brand from Thailand is PromPlus sweet whole kernel corn.
- The label of two out of 10 GM-positive foods had claimed no use of GM ingredients but was found to be positive (Mori-Nu tofu and PromPlus sweet whole kernel corn) and the labels of four mentioned use of GM ingredients.
- No Indian packaged food sample tested was GM positive.

Infant food: 25 per cent (2/8) samples tested were GM positive.
- Both positive samples were imported and marketed by the same company (Abbott Healthcare Pvt. Ltd). One (Similac Isomil), which is imported from the Netherlands, is a lactose-free infant milk-substitute soy infant formula. The other (Similac Alimentum), imported from the US, is a hypoallergenic infant formula.
- No positive sample mentioned GM on its label.

Table 3: GM-positive food product samples

Food product/ category	Brand/ company	Manufacturer/distributer/ importer	Relevant ingredients	Labelling with respect to GM	Country of origin
Oils					
Canola	Candrop	Imported, packed and marketed by Century Edible Cooking Oils Pvt. Ltd, Punjab	Imported rapeseed low erucic acid oil (canola oil). Product of Canada	GMO free	Canada
Canola	Farrell	Imported by Jindal Retail (India) Pvt. Ltd, Delhi	Edible vegetable oil. Imported refined rapeseed oil low erucic acid oil	-	UAE
Canola	Hudson	Packed for and marketed by Dalmia Continental Pvt. Ltd, Delhi	Imported refined canola oil. Edible grade oil. Extracted from Canadian oilseeds	-	UAE
Canola	Jivo	Imported, packed and marketed by Jivo Wellness Pvt. Ltd, Delhi	Imported refined rapeseed oil low erucic acid oil	-	Canada
Cottonseed (kapasia tel)	Ankur	Manufactured and packed by Ambar Protein Industries Ltd, Ahmedabad	Refined cottonseed oil	-	India
Cottonseed	Ginni	Packed by Bunge India Pvt. Ltd, Punjab	Refined cottonseed oil	-	India
Cottonseed (kapasia tel)	Tirupati	Marketed by N.K. Proteins Pvt. Ltd, Ahmedabad	Refined cottonseed oil	-	India
Cottonseed	Vimal	Manufactured by Vimal Oil & Foods Ltd, Ahmedabad	Refined cottonseed oil	-	India
Crude cottonseed	Unknown	Unknown, Gujarat	Crude cottonseed	-	India
Packaged foods					
Original syrup	Aunt Jemima	Distributed by the Quaker Oats Company, Chicago Imported and marketed by Newage Gourmet Foods, Delhi	Corn syrup, high-fructose corn syrup (HFCS)	Produced with Genetic Engineering	USA
Dark corn syrup	Karo	Produced by ACH Food Companies Inc., USA Imported and marketed by Newage Gourmet Foods, Delhi	Corn syrup, refiners syrup	Produced with Genetic Engineering	USA
Pancake syrup original	American Garden	A product of American Garden Co., New York Imported by Bajoria Foods Pvt. Ltd, Mumbai	High-fructose corn syrup (HFCS), corn syrup	-	USA
Froot Loops (sweetened multigrain cereal)	Kellogg's	Distributed by Kellogg Sales Co., USA Imported and marketed by Newage Gourmet Foods, Delhi	Corn flour blend, whole grain yellow corn flour, degerminated yellow corn flour, soybean and/or cottonseed oil	-	USA

Food product/ category	Brand/ company	Manufacturer/distributer/ importer	Relevant ingredients	Labelling with respect to GM	Country of origin
Crispy corn snacks (original flavour)	Bugles	Distributed by General Mills Inc. Minneapolis, USA Imported and marketed by Newage Gourmet Foods, New Delhi	Degermed yellow corn meal	-	USA
Popcorn Hot N' Spicy	American Garden	Product of American Garden, USA Imported and distributed by Bajoria Foods Pvt. Ltd, Mumbai	Partially hydrogenated soybean oil, popcorn, contains milk and soy	-	USA
Butter and Garlic Croutons made from Texas Toast Bread	Mrs. Cubbison's	Imported and marketed by Newage Gourmet Foods, New Delhi	Canola oil, high-fructose corn syrup	Partially produced with Genetic Engineering	USA
Corn puffs (naturally fruit flavoured sweetened)	Trix	Distributed by General Mills Sales Inc., USA Imported and marketed by Newage Gourmet Foods, New Delhi	Whole grain corn, corn meal, corn syrup, canola oil	Produced with Genetic Engineering	USA
Silken tofu (extra firm)	Mori-Nu	Manufactured by Pacific Nutritional Foods Inc., USA Distributed by Morinaga Nutritional Foods Inc., California Imported by Olive Tree Trading Pvt. Ltd, Pune	Soybeans, isolated soy protein	Non-GMO Project Verified	USA
Sweet whole kernels corn	PromPlus	Produced and packed by Riverquai International Food Industry Co. Ltd Imported by Guru Kirpa Impex, Delhi	Sweet kernel corn	Non-GMO	Thailand
Infant foods					
Soy infant formula (lactose-free infant milk substitute, soy infant formula)	Similac Isomil (up to 24 months)	Manufactured by Abbott Laboratories BV, Netherlands Imported and marketed by Abbott Healthcare Pvt. Ltd, Mumbai	Hydrolysed corn starch, soy protein isolate (15.61%), soy oil	-	Netherlands
Hypoallergenic infant formula	Similac Alimentum (from birth onwards)	Manufactured by Abbott Laboratories Imported and marketed by Abbott Healthcare Pvt. Ltd, Mumbai	Maltodextrin, soy oil, emulsifier modified corn starch	-	USA

GM food policy framework in India

Overview and history: Cracks in the approval process for GM processed foods
Since 1989, the Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change (MoEF&CC) has been responsible for approving commercial cultivation of GM crops as well as the manufacture, import and selling of processed foods made from GM ingredients. So far, Bt cotton has been approved for cultivation. After the enactment of the Food Safety and Standards Act in 2006, the GEAC wanted to restrict itself to approval of living modified organisms (LMOs) and shift the task of approval of processed foods to the FSSAI for which a notification was also issued in 2007. In response, the Ministry of Health and Family Welfare (MoHFW) requested the MoEF&CC in the same year to continue regulating processed foods until the FSSAI was ready to do so in a scientific manner. The notification was kept in abeyance until 2016, making the GEAC responsible for approvals of processed foods, with no accountability of the FSSAI in practice despite Section 22 of the Food Safety and Standards Act, 2006 (FSS Act) stating that GM foods shall not be manufactured, sold, distributed or imported until the FSSAI approves them. Meanwhile, in 2013, the Legal Metrology (Packaged Commodities) Rules, 2011 were amended to mandate that packages containing genetically modified foods bear the words 'GM' on its principal display panel. This rule was inconsistent with the fact that GM foods are not allowed in India and in fact created the false perception that GM food was allowed. The FSSAI's new draft labelling regulation of April 2018 aims to address the issue through labelling of GM foods (see *Table 4: Policy and gaps* and *Table 5: Timeline of GEAC-related events for approval of GM foods in India*).

In February 2018, the Union minister, MoHFW, on being asked about the vacuum in regulation of GM foods, made the following noteworthy statements in the Lok Sabha[4]:

- Genetically Engineered Organisms (GEOs) or LMOs, intended for direct use as food or for processing as food, would continue to first require approval from the GEAC for environmental safety and then require approval of the FSSAI for food safety.
- Food or processed food containing GM ingredients produced from but not containing LMOs or GEOs would require approval of FSSAI.
- No standards for GM foods have been laid down/notified by the FSSAI. However, even in the absence of specific standards for GM foods, as per Section 22 of Food Safety and Standards Act, 2006, GM foods are not allowed to be manufactured, imported or sold in the country.

Table 4: Policy and gaps

Policy	Gaps (policy and implementation)
Section 22 of the Food Safety and Standards Act, 2006 provides that no person shall manufacture, distribute, sell or import any genetically modified articles of food except as provided under this Act and regulations made thereunder.	The FSSAI and the MoHFW have maintained that no GM food product has been approved by FSSAI. However, the CSE study confirms the illegal presence of imported and domestically manufactured GM foods in the Indian market.
The FSSAI approves cottonseed oil in India. The FSS (Food Product Standards and Additives) Regulation, 2011 sets parameters for cottonseed oil and solvent extracted cottonseed flour. It also lists cottonseed oil as a permanent ingredient in vanaspati.	The Regulation neither recognizes the possibility of cottonseed oil being derived from GM cotton nor has the FSSAI given any specific approval for cottonseed oil extracted from GM cotton. This makes GM cottonseed oil available in the Indian market illegal.
In June and December 2017, the FSSAI approved through two separate orders the import of 95 specialty foods—foods for special dietary needs—for inborn errors of metabolism and hypoallergenic conditions.[5]	The orders do not mention that the presence or absence of GM in these products was considered while approving. Moreover, the FSSAI has not given approval to any GM foods so far. However, the CSE study found a GM-positive product (Similac Alimentum) approved through the June 2017 order.
As per Rule 6(7) of the Legal Metrology (Packaged Commodities) Rules, 2011, every package containing GM foods shall bear at the top of its principal display panel the letters 'GM'.	The CSE study found 13 products (domestically manufactured and imported) that tested GM positive but did not mention the use of GM ingredients on their labels. Also, the requirement of mentioning 'GM' as per these Rules is different from the mandate in the draft FSS (Labelling and Display) Regulations, 2018, i.e. 'contains GMO/ Ingredients derived from GMO', which will create confusion.

Table 5: Timeline for GEAC related-events for approval of GM food in India

Month and year	Event
1989	GEAC approval was made mandatory for manufacturing, selling or importing food containing GM ingredients (1989 Rules, under EPA).
March 2002	GEAC granted permission for commercial release of three varieties of Bt cotton[6]
May 2006	Draft notification (not finalized) issued to amend Prevention of Food Adulteration Rules, 1955 seeking to make GEAC approval for GM foods and its labelling mandatory
August 2006	Section 22, Food Safety and Standards Act, 2006 prohibits GM foods unless provided under the Act or regulations under it.
August 2007	Notification issued to amend the 1989 Rules to exclude processed food from the purview of the GEAC.[7]
December 2007	The MoHFW wrote to the MoEF&CC requesting it to continue regulating processed foods derived from GM ingredients until the FSSAI is able to look into the matter in a scientific manner. Thereon, the August 2007 notification was kept in abeyance till 31 March 2016.
January 2013	The Legal Metrology (Packaged Commodity) Rules, 2011 modified[8] to mandate that every package containing GM food shall, at the top of its principal display panel, bear the words 'GM'
April 2017	GEAC admitted that there is a vacuum in the law with regard to regulation of imports of GM processed foods. It decides to take up the issue with the FSSAI and until the FSSAI is ready, GEAC will regulate the matter.[9]
March 2018	GEAC decides that application for import of oil and raw and refined sugar is to be sent to FSSAI; application for import of grains is to be handled by GEAC; application for import of animal feed from GM corn and soy is to be submitted as per the DDGS (Dried Distillers Grain Soluble) guidelines and comments of the Department of Dairying Animal Husbandry and Fisheries to be sought.[10]

Note: In 2007, the GEAC gave one-time approval to the Solvent Extractors' Association of India to import GM soya bean oil derived from Roundup Ready soybean for the purpose of consumption. After that, the GEAC has allowed the import of soya bean oil five times and the import of canola oil once on a case-by -case basis to companies in the agrochemical business. The GEAC also allowed the import of Doritos from Singapore once in 2009.

GM food labelling in different countries

GM labelling approaches

Labelling of GM foods complements safety assessment while regulating GM foods. Taking into consideration its significance, countries have adopted a mix of different approaches to labelling which include:

- Mandatory or voluntary approach: While the EU, Australia, New Zealand, Brazil, South Korea and a few other countries have adopted mandatory labelling, USA and Canada permits voluntary labelling of GM foods. Some countries also permit voluntary GM-free labelling.
- Thresholds set for labelling exemption: Thresholds are based on quantity of GM DNA or weight of the GM ingredient in the total product. For example, Japan has adopted a limit of five per cent of GM ingredients (by weight) in the product, whereas the EU provides a limit of 0.9 per cent GM DNA per ingredient in view of adventitious or technically unavoidable presence, which the producer is to prove (see *Table 6: GM food labelling regulations in different countries*).

Proposed labelling of GM foods in India

In India, as per Section 22 of the FSS Act, GM food is illegal until the FSSAI approves it, which it hasn't done so far. The FSSAI has recently proposed the draft FSS (Labelling and Display) Regulations, 2018, which also seeks to make labelling of GM food mandatory. These regulations have not been finalized yet. The regulation provides, 'all food products having total Genetically Engineered (GE) ingredients 5 per cent or more shall be labelled. The total GE ingredients shall be of top three ingredients in terms of their percentage in the product.'

Clearly, the proposed threshold limit of five per cent for exemption is very relaxed, particularly for a country in which no edible GM crop is allowed to be cultivated. It seems to heavily rely on food manufacturers' self declaration of GM ingredients in a product. Further, it neither specifically addresses unintentional contamination nor does it mention specifications on size and colour of the text and placement of label as, for example, on the principal display panel. It also does not propose a symbol-based labelling as in Brazil; symbol-based labelling could prove very effective in India given the several languages other than English spoken here.

Double standards—Self-declaration for GM foods versus certification for organic food

In December 2017, the FSSAI notified the Food Safety and Standards (Organic Foods) Regulations,[11] aimed at regulating organic foods in the country, primarily through certification and labelling. A close look at the regulation underlines the contrary approaches that the apex food regulator has adopted towards labelling of organic foods, which are considered safe, and GM foods, the safety of which has yet not been established. For example, a food commodity requires certification for it to be labelled 'organic' by the producer/farmer. Certification herein means that a third-party industry or group of farmers certify that sustainable agricultural practices have been followed for two to three years and there has been no use of chemicals in producing and processing. The law mandates either third-party certification, which is cost-prohibitive, or certification by a group of farmers under the participatory guarantee system (PGS), which also has its own set of limitations related to implementation.

The key point is that too much is to be done by the farmer or producer to label a food which is considered safe. In contrast, the proposed five per cent threshold limit for multiple ingredients for exempting GM labelling is not only relaxed but counterintuitive. The problem magnifies, since this would largely be based on self-declaration by the Industry, which would be difficult to monitor by an enforcement agency.

Table 6: GM food labelling regulations in different countries

Country/region	Mandatory/ voluntary	Text to be labelled	Threshold set (for exemption from labelling)
European Union[12]	Mandatory (GMO-free labelling is voluntary)	List of ingredients must indicate 'genetically modified' or 'produced from genetically modified [name of the organism]'	Up to 0.9 per cent GM DNA (per ingredient) in view of adventitious or technically unavoidable presence
Australia	Mandatory[13] (GMO-free labelling is voluntary)	Packaged food: 'genetically modified' either next to the name of the food (e.g. 'genetically modified soy beans'), or in association with the specific GM ingredient in the ingredient list e.g. 'soy flour (genetically modified)' Unpackaged food: Information must accompany or be displayed with the food	Unintentional presence of up to one per cent (per ingredient by weight) of an approved GM ingredient in a non GM food[14]
New Zealand[15, 16]	Mandatory	'genetically modified'	Same as in the case of Australia
Brazil[17]	Mandatory	 Transgenic symbol	Up to one per cent of an approved GMO ingredient (by weight)
Saudi Arabia[18, 19]	Mandatory	'genetically modified' or 'produced from genetically modified [name of the ingredients]' Clear, easy to read in parentheses immediately following the ingredient(s) concerned, in same font size and different colour	Less than one per cent GE content (DNA or protein) in a product

Country/region	Mandatory/ voluntary	Text to be labelled	Threshold set (for exemption from labelling)
South Korea[20]	Mandatory (seven approved GM food crops and food products containing these crops are subject to labelling) For crops/products other than these, GM-free claims are not allowed	On the principal display panel or on ingredients panel using stickers, printed label or stamp Font size of 12 points	Up to three per cent unintentional presence of approved GM components in non-GMO ingredient is allowed
Thailand[21]	22 categories of food products listed which are subject to labelling requirements	Single-ingredient foods: 'genetically modified' in conjunction with, or in close proximity to, the name of foods, as in 'genetically modified corn' or 'tofu produced from genetically modified soybean' Multi-ingredient foods: Labels should include a statement of 'genetically modified' in conjunction with, or in close proximity to, or under the names of top three main ingredients of the food product such as 'genetically modified corn starch' etc.	Five per cent GE content of the product
Japan[22]	Mandatory Applicable to a list of 33 processed-food categories derived from eight approved GM crops Voluntary GM-free labelling permitted only for these 33 categories if not been produced using any of the approved eight GM ingredients (and certified as being segregated from GM products while handling) or if GM DNA or protein cannot be detected.	As the case may be: 'GM Ingredients' 'GM Ingredients Not Segregated' 'Non-GM'	Applicable to these 33 processed foods categories: A food product having less than five per cent by weight of approved GM ingredients

Country/region	Mandatory/ voluntary	Text to be labelled	Threshold set (for exemption from labelling)
Canada[23]	Voluntary labelling permitted	Certain terms of labelling are considered appropriate as for example, in single-ingredient products, 'this corn oil is a product of genetic engineering' For multi-ingredient products: These chips are made from potatoes that are not a product of genetic engineering and made with oil from canola that is a product of genetic engineering	Accidental inclusion of an ingredient from a GM crop that comprises less than five per cent (by weight) of the food
USA[24, 25]	Voluntary labelling permitted	A guidance document (not legally enforceable) provided for industry. Some examples of declarations: 'Genetically engineered' or 'This product contains cornmeal from corn that was produced using modern biotechnology'. 'Some of our growers plant soybean seeds that were developed through modern biotechnology to be drought tolerant'.	No threshold Draft Rule on National Bioengineered Foods Disclosure Standards (open for comments)—three options for threshold limit: Five per cent per ingredient by weight (inadvertent or technically unavoidable contamination); or 0.9 per cent per ingredient by weight (inadvertent or technically unavoidable); or Weight of bioengineered ingredients up to five per cent of the total weight of the product.
India[26] (Draft Regulations)	Mandatory	'Contains GMO/Ingredients derived from GMO'	Less than 5 per cent of total Genetically Engineered (GE) ingredients. Total GE ingredients shall be top three in terms of their percentage in the product.

qPCR-based screening should be used as an enforcement tool in India

Quantitative PCR (qPCR) enables researchers to screen for GM DNA and quantify it in a test food sample. Quantification can be represented in two ways. First, it can be used to represent the percentage of GM DNA in a food sample, i.e. the proportion of GM DNA in relation to the total crop-specific DNA (taxon-specific). Second, it can be used to quantify the weight of GM ingredient present in a food sample.

The Indian draft labelling regulation sets a threshold for exemption limit based on weight of the ingredient. But there are two key issues that would make the proposed standard difficult to implement in India. First, quantification is an expensive process. While the average cost of screening is about Rs 10,000 per sample, the cost of quantifying a GM ingredient in a product could be several times higher—in the range of Rs 25,000-60,000, depending upon the number of GM crops and events a food sample is tested for. Second, quantification to determine the weight of a specific GM ingredient is possible if it is known which GM crops with specific GM events are to be checked for and their certified reference materials are available for testing. Since India doesn't allow GM cultivation and import of GM foods, this would be a challenge.

Therefore, in the Indian scenario, the techno-economic feasibility of using qPCR for screening for GM DNA is much higher and should be adopted as an enforcement tool.

Safety of GM foods

Safety of GM crops and products has been a matter of concern for human health. Risk assessment on a case-by-case basis is critical for a country-level decision to allow or restrict GM foods. This is because various GMOs have different genes, which are inserted in multiple ways. Besides, studies used to evaluate the risk must take into account different populations and geographies.[27] The WHO–FAO-led Codex Alimentarius[28] provides detailed guidelines for assessing risks associated with GM foods. Typically, the following parameters are considered for risk assessment:

- **Toxicity**—acute, sub-chronic and chronic
- **Allergenicity**, i.e. the potential to provoke allergic reaction due to cross-reaction with other allergens or from new unknown GM proteins
- **Composition analysis** of major and minor nutrients to ascertain new or greater risks to nutritional status compared to traditional counterparts
- **Nutritional effects** associated with genetic modification that could arise if GM DNA is inserted into the crop genome at a location where it modifies the existing DNA such that the nutritional content of the crop alters.
- **Stability of inserted gene** to avoid its unintended escape into cells of the body or to bacteria in the gastrointestinal tract. This is particularly relevant if antibiotic-resistant genes, used as markers while creating GMOs, were to be transferred.
- **Unintended effects** that could result from the gene insertion leading to formation of new or changed patterns of metabolites.

The Indian Council of Medical Research (ICMR) has published *Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants,* (2008, updated 2012),[29] based on guidelines by Codex Alimentarius, i.e. *Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants* (2003).

Status check: Safety of GM foods in India

In December 2017, a Parliamentary Committee report[30] that examined the impact of GM crops on environment and human and animal health identified huge gaps with respect to the safety of GM crops. It noted the following key issues:

- There has been no Indian scientific study carried out so far to study the impact of GM crops on human health.
- Long-term effects on the human health have not been studied.
- The Department of Health Research has not taken any action with regard to examination of impact of GM crops on human health.
- The government should reconsider its decision to commercialize GM crops in the country as it has not been scientifically proven that GM crops have no adverse impact on human health. It is relying solely on studies that have not been done in India rather than on our own population and in the context of our climate and environment.
- It is very late in the day for the FSSAI to take a decision to label GM foods imported into the country. However, the committee strongly recommends that labelling on GM foods must be done with immediate effect.

ICMR guidelines: Key parameters for risk analysis of GM foods

Assessment of possible toxicity

- Chemical nature, function, concentration of newly expressed substance
- Current dietary exposure and possible effects on population subgroups
- Detailed analysis of new protein (amino acid homology with known toxins) and its stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems
- Acute oral toxicity of new protein
  The type of studies may include those on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/ carcinogenicity, reproduction and development toxicity

Assessment for possible allergenicity

- Detailed protein analysis (amino acid homology with known allergens)
- Susceptibility of new protein to enzyme digestion (pepsin resistance)
- Specific serum screening (serum immunological tests of new protein)

Compositional analysis

- Key nutrients or anti-nutrients that may have a substantial impact in the overall diet
- Major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients)
- Minor compounds (minerals, vitamins)
- Key toxicants
- Proximate analysis (ash, moisture content, crude carbohydrate, crude protein, crude fat)
- Predictable secondary metabolites, physiologically active (bioactive) substances

Intended nutritional modifications

- Bioavailability of the modified nutrient and its stability with time, processing and storage

Unintended effects

- Agronomic/phenotypic characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization

The committee also pointed out similar issues with respect to safety studies to evaluate the impact of GM crops on animal health and environment, both being potential routes through which GM crops and foods could impact human health.

Recommendations

While the FSSAI, India's apex food regulator, has not allowed any GM food in India, the CSE study shows that GM foods are available in the Indian market in the form of imported packaged foods and domestically produced cottonseed oil. The FSSAI must in the interest of public health and informed consumer choice take the following necessary actions at the earliest.

- **Prosecute companies and traders for bringing illegal GM products in the market**
  The CSE study has identified certain GM foods available in Indian markets. The FSSAI must identify all illegal GM foods, ensure that they are not available in the Indian market and take necessary legal action against concerned companies and traders.

- **Set up a stringent system for approving domestically produced and imported GM food products**
  Safety assessment of GM foods is a first and critical step and must be the central basis of the GM-food approval process. The FSSAI must set up such a system for both domestically produced and imported GM food products. The assessment must be done on a case-to-case basis and not rely only on manufacturer data and short-term studies or studies based on poor design. The results of assessments and proceedings should be put out in the public domain.

- **Enact stringent GM labelling laws—the proposed draft is weak and must be strengthened**
  The current proposed draft labelling law is weak. The exemption limit of five per cent for multiple ingredients is very relaxed. Since it is based on the weight of GM ingredients, determination of which is an expensive process, implementation will have to heavily rely on food manufacturers' self declaration of GM ingredients. This could lead to a scenario wherein GM foods are available in the market without being labelled and with no approval process.

  Therefore, India's GM labelling regulations must be based on stringent exemption limit and qualitative screening as an enforcement tool. This means that all products wherein GM ingredients are used must be labelled even if the final product does not contain GM DNA or protein. The threshold limit for GM labelling exemption should be set at one per cent GM DNA and not on the weight of the ingredient. The exemption limit should only be given for inadvertent contamination of GM ingredients. The enforcement mechanism should be based on a qualitative screening of the GM DNA (such as through the qPCR). The onus of proving unintentional presence should be put on the manufacturer if the samples are found positive in the screening process.

  To make GM labelling more consumer-friendly, the FSSAI must develop a symbol-based label along with the text. Since English is not the preferred language in many parts of the country and most food packages are labelled in English, it is likely that only text-based labelling defeats the purpose. Labelling could be along the lines of a green or brown 'dot in a square' symbol developed for 'veg' or 'non veg' or the recently developed green

'tick' to indicate 'jaivik', i.e. organic food, on the front-of-pack. In addition, details of the GM ingredient used should be mentioned along with other text.

- **FSSAI must set up laboratories for testing GM foods**
  In order to curb the availability of illegal GM foods in Indian markets, the FSSAI must set up laboratories for screening of GM foods, which help in effective monitoring and enforcement.

Annexure 1: Details of GM-negative test samples

Food product/ category	Brand/ company	Manufacturer/distributer/ importer	Relevant ingredients	Labelling with regard to GM	Country of origin
Oils					
Canola	Wagga Wagga (Diabetes care)	Manufactured and packed by Riverina Oils & Bio Energy Pty Ltd, Deepdene, Australia Imported and marketed by Agro Global Resources (P) Ltd, Noida, Uttar Pradesh. Packed by Mann Feeds (P) Ltd, Faridabad, Haryana	Edible vegetable oil. Imported refined rapeseed oil (canola oil) low erucic acid	Made from Non-GMO Canola seeds	Australia
Canola	Wagga Wagga (Heart care)	Manufactured and packed by Mann Feeds (P) Ltd, Faridabad, Haryana Marketed by Agro global Resources (P) Ltd, Noida, Uttar Pradesh	Imported refined rapeseed oil low erucic acid (80% by wt), imported refined olive oil (20% by wt). Seeds from Australia.	-	India
Canola	Borges	Manufactured by Borges Agricultural and Industrial Edible Oils, Spain. Imported and distributed by Borges India (P) Ltd, New Delhi	Edible refined rapeseed low erucic acid oil	-	Spain
Soya bean	Fresh & Pure	Manufactured and packed by Cian Agro Industries & Infra Ltd, Maharashtra Marketed by Future Consumer Ltd, Mumbai	Refined soya bean oil	-	India
Soya bean	Fortune Soya Health	Manufactured by Adani Wilmar Ltd, Ahmedabad, Gujarat	Refined soya bean oil	-	India
Soya bean	Nature Fresh Acti Lite	Manufactured and marketed by Cargill India Pvt. Ltd, Gujarat and Delhi	Soya bean oil	-	India
Corn rice bran	Saffola Tasty	Manufactured and marketed by Marico Limited, Mumbai	60 % corn oil, 40 % rice bran oil	-	India
Packaged foods					
Soya vadi	Golden Harvest	Manufactured and packed by Future Consumer Limited, Samaypur, Delhi	Not mentioned	-	India
Mini soya chunks (mini soya vadi)	Fortune	For processing and packing unit: Adani Wilmar Ltd, Vidisha, MP Marketed by Adani Wilmar, Gujarat	Soya flour	-	India
Soya chunks	Nutrela	Manufactured and packed by Ruchi Soya Industries Limited, Indore, MP	100% defatted soya	-	India

Food product/ category	Brand/ company	Manufacturer/distributer/ importer	Relevant ingredients	Labelling with regard to GM	Country of origin
Soya chunks	Ektaa	Manufactured and packed by Future Consumer Limited, MP Marketed by Future Consumer Limited, Mumbai	Not mentioned	-	India
Dark soy sauce	Pantai (norasingh)	Manufactured by Pantainorasingh Manufacturer Co. Ltd, Thailand	Soya bean extract (52%), soya bean	-	Thailand
Dark soy sauce	Ong's	Manufactured by Bachul Food Industries (PTE) Ltd, Singapore Imported in India by Suresh Kumar & Co. (Imtex) Pvt. Ltd, Delhi	Soya bean extract (38%), soya beans	-	Singapore
Soy sauce classic	American Garden	Product of American Garden, USA Imported and marketed by Bajoria Foods Pvt. Ltd, Mumbai	Hydrolysed soy protein, high fructose corn syrup	-	USA
Corn flakes + (with real honey)	Bagrrys	Manufactured by Bagrrys India Ltd, Baddi, HP Marketed by Bagrrys India Ltd, Delhi	Corn grits (85%), invert syrup	-	India
Corn flakes	Kellogg's	Manufactured by Kellogg India Pvt. Ltd Maharashtra	Corn grits, invert syrup	-	India
Sweet corn chicken (instant everyday soup)	Keya	Manufactured by Keya Foods International Pvt. Ltd, Kerala	Corn	-	India
Sweet corn soup	Ching's Secret	Manufactured by Capital Foods Pvt. Ltd, Gujarat Marketed by Capital Foods Pvt. Ltd	Corn starch, sweet corn	-	India
Sweet corn chicken soup	Knorr Classic	Manufactured by Hindustan Unilever Limited, Nashik and Avalon Cosmetics Pvt. Ltd, Nashik Marketed by Hindustan Unilever Ltd (HUL), Mumbai	Maize starch, corn (5.8%)	-	India
Frozen sweet corn	Safal	Packed and marketed by Mother Diary Fruits & Vegetables Pvt. Ltd, Haryana	Individually quick frozen sweet corn kernels	-	India
Sweet corn kernel	Veg affaire	Packed by Integrated Food Park Pvt. Ltd, Karnataka Marketed by Future Consumer Enterprise Limited, Mumbai	Individually quick frozen sweet corn kernels	-	India

Food product/ category	Brand/ company	Manufacturer/distributer/ importer	Relevant ingredients	Labelling with regard to GM	Country of origin
Whole kernel corn	Del Monte	Manufactured by Field fresh foods Pvt. Ltd, Gurugram, Haryana Marketed by Del Monte (India)	Corn	-	India
Corn (original naturally sweet)	Green Giant	Manufactured for General Mills International SARL, Switzerland, General Mills, UK	Sweet corn	-	France
Popcorn (classic salted)	ACT II	Manufactured by Agro Tech Foods Limited, Secunderabad	Popping corn, refined edible palmoline oil	-	India
Sriracha lime cheese popcorn	PVR	Manufactured and marketed by Zea Maize Pvt. Ltd, Haryana	Corn (62%), edible vegetable oil	Non-GMO corn	India
American Sweet Corn	Yummiez	Marketed by Godrej Tyson Foods Ltd, Mumbai	Sweet corns	-	India
Pringles potato crisps (original)	Kellogg's	Manufactured by Super Food Technology, Malaysia Imported and marketed by Kellogg India Pvt. Ltd, Maharashtra	Corn flour	-	Malaysia
Potato crisps	Lays (Stax Original)	Manufactured for Frito-Lay Inc., North America Imported and marketed by Newage Gourmet Foods, New Delhi	Cottonseed oil, corn oil, soy lecithin, contains a soy ingredient	Partially produced with Genetic Engineering	Mexico
Tortilla chips (cool ranch flavoured)	Doritos	Manufactured for PepsiCo Inc. by Frito-Lay Inc., USA Imported and marketed by Newage Gourmet Foods, New Delhi	Corn, corn oil, canola oil, corn starch, corn syrup solids, maltodextrin made from corn	-	USA
Crunchy peanut butter	American Kitchen	Manufactured by American Kitchen, Delaware Imported by Sunbeam Mercantile Ventures P Ltd, Kochi	Hydrogenated vegetable oil (cottonseed and/or rapeseed oil)	-	USA
Multigrain Cheerios (5 whole grains)	Nestle	Imported and marketed by Newage Gourmet Foods, Delhi	Wholegrain corn flour (2%), partially inverted brown sugar syrup	-	UK
Aloo bhujia	Haldirams	Manufactured and marketed by Haldirams Snacks Pvt. Ltd, India	Cottonseed oil, corn oil	-	India
Pop tarts toaster pastries (frosted blueberry)	Kellogg's	Distributed by Kelloggs Sales Co., MI Imported and marketed by Newage Gourmet Foods, New Delhi	Corn syrup, high fructose corn syrup, soybean oil, corn flour, soy lecithin, corn starch, contains wheat and soy ingredients	-	USA

Food product/ category	Brand/ company	Manufacturer/distributer/ importer	Relevant ingredients	Labelling with regard to GM	Country of origin
Soya milk (strawberry)	Soyfresh	Owner of the rights of manufacture: Ace Canning Corporation SdnBhd Manufactured by Okka Ace Lot 39, Keluli1 S.A., Malaysia Imported and marketed by DC Johar & Sons (P) Ltd. Cochin, India	Soybean extract (85%), corn oil Made from 100% Canadian soybean	-	Malaysia
Panchrattan Namkeen	Haldirams	Manufactured and marketed by Haldirams Snacks Pvt. Ltd, India	Cottonseed oil, corn oil	-	India
Chicken corn coating (Mingles bucket)	KFC	KFC, Gurugram	Corn flour	-	India
Infant foods					
Infant formula	Similac IQ+ 1	Manufactured by Abbott Manufacturing Singapore Private Limited, Singapore (A subsidiary of Abbott Laboratories, USA) Imported and marketed By Abbott Healthcare Pvt. Ltd, Mumbai	Soy oil	-	Singapore
Follow-up formula for older infants	Enfamil A+ 3 (from 12 to 24 months)	Imported by Mead Johnson Nutrition India Pvt. Ltd, Mumbai, Maharashtra	Vegetable oil, low erucic rapeseed oil, corn syrup solids, corn oil	-	Thailand
Hypoallergenic formula	Nutramigen LGG	Manufactured by Mead Johnson, Netherlands Imported by Mead Johnson Nutrition (India) Pvt. Ltd, Mumbai, Maharashtra. LGG is a registered trademark of Valio Ltd, Finland	Corn syrup solids, soybean oil, modified corn starch	-	Netherlands
Lactose and sucrose free infant milk substitute	Dexolac Nusobee Soya (up to 24 months)	Manufactured and marketed by Nutricia International Private Limited, Punjab (A subsidiary of Danone)	Soya oil, soya protein isolate	-	India
Follow-on milk	SMA pro 2	Manufactured by SMA Nutrition (Registered Trademark of Societe des Produits Nestle SA)	Emulsifier (soy lecithin), rapeseed oil	-	Ireland
Lactose and sucrose free infant milk substitute, type II	Zerolac	Manufactured By: Raptakos Brett & Co. Ltd, Mumbai, Maharashtra	Soya protein isolate (16.2%)	-	India

Food product/ category	Brand/ company	Manufacturer/distributer/ importer	Relevant ingredients	Labelling with regard to GM	Country of origin
Protein supplements					
Protein supplement for adults	Prosure (delicious banana flavour)	Manufactured by Abbott Laboratories, Spain Imported and marketed by Abbott Healthcare Pvt. Ltd. Mumbai	Soya oil, soya polysaccharide, soya lecithin	-	Spain
Soybean-based nutritional beverage mix	Protinex (elaichi flavour, low fat)	Manufactured and marketed by Nutricia International Pvt. Ltd, Punjab (Protinex is a registered trademark of Danone Asia Pacific Holdings PTE Ltd)	Soya protein isolate, corn flour	-	India

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India's apex food regulator—the Food Safety and Standards Authority of India (FSSAI)—does not allow manufacture, distribution, sale or import of genetically modified (GM) foods in the country. But this CSE study shows that GM foods are available in the Indian market in the form of imported packaged foods and domestically produced cottonseed oil.

The FSSAI's new draft labelling regulation of April 2018 aims to address the issue but the proposed law is weak. This report recommends actions for the FSSAI to take in the interest of public health and informed consumer choice with regard to regulation of GM foods.

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