

GENETICALLY MODIFIED PROCESSED FOODS IN INDIA

Need to Curb Illegal Sales
in the Indian Market

PRESS CONFERENCE
JULY 26, 2018



**Centre for Science and
Environment, New Delhi**



CSE's Pollution Monitoring Laboratory (PML)

- Set up in **2000**, with state of the art equipment for monitoring air pollution, water pollution and food contamination
- **Tests** for pesticide, antibiotics, heavy metals and conducts microbiological and molecular biology studies
- Investigates issues of **public health** concern and responds to community requests
- Puts out **independent information** in public domain for ecological security



Wide-range of studies conducted by PML for about two decades

LAB STUDIES:

FOOD

2003: Pesticide residues in bottled water

2003 & 2006: Pesticides in soft drinks

2009: Transfats in edible oil

2010: Antibiotics in honey

2011: Caffeine in energy drinks

2012: Nutritional analysis of junk food

2014: Antibiotic residues in chicken meat

2016: Potassium bromate/iodate in bread

CONSUMER PRODUCTS

2009: Lead in paints

2010: Pthalates in toys

2014: Heavy metals in cosmetics

ENVIRONMENT

2001: Endosulphan poisoning

2005: Pesticides in the blood of Punjab cotton farmers

2009: Ground water contamination in and around UCIL, Bhopal

2012: Mercury poisoning in Sonbhadra, UP

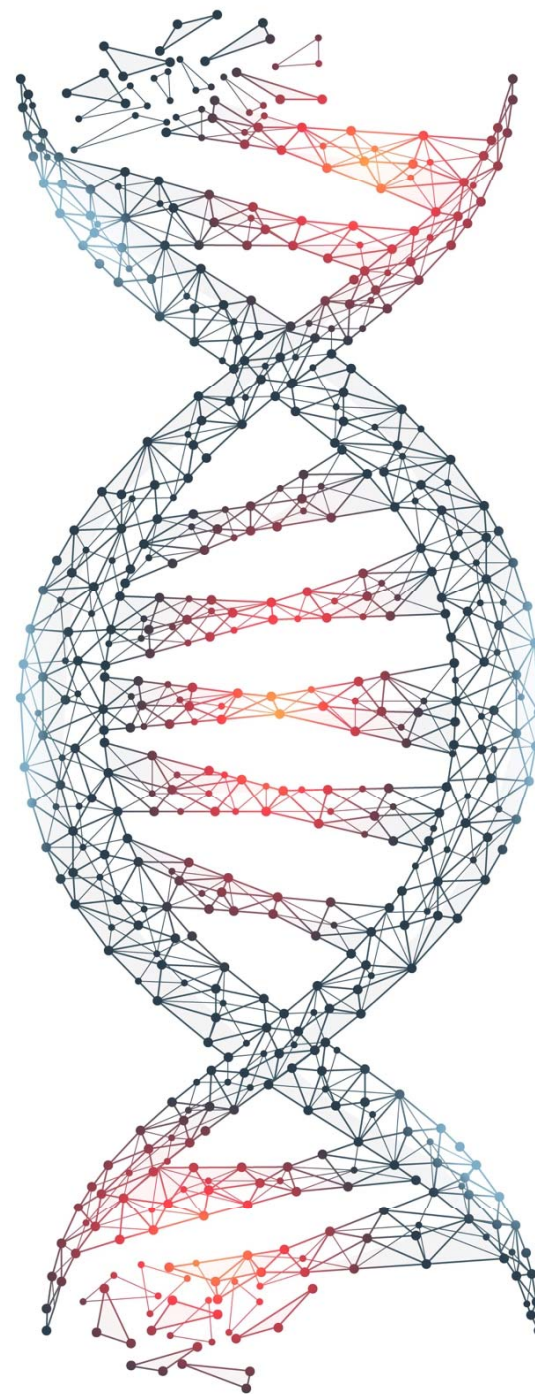
2017: Antibiotic resistance in poultry environment



OBJECTIVE

**To detect the presence of
genetically modified (GM)
processed foods available in
the Indian market**

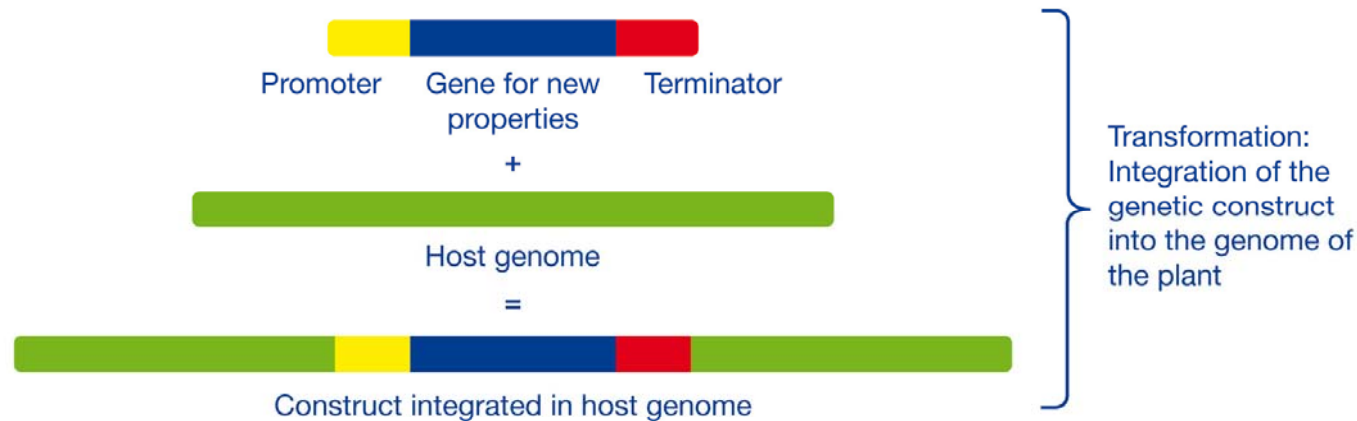
Rajarshi Banerjee, PhD
Head, PML, CSE





Genetically Modified (GM) Foods and Genetically Modified Organisms (GMOs)

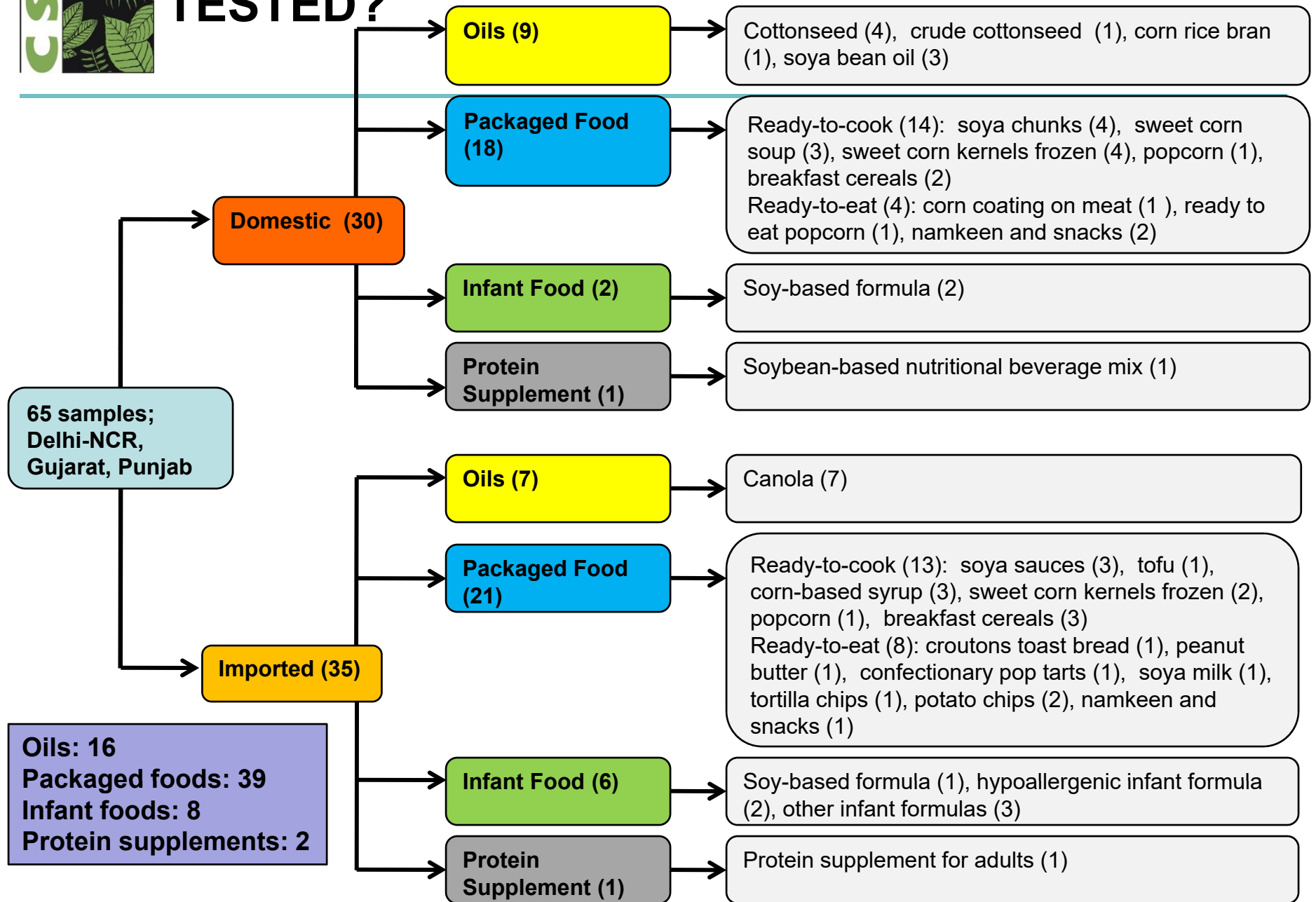
- **GM Food:** Food produced from or using genetically modified organisms (GMOs)
- **GMO:** Any organism whose genetic material has been altered using genetic engineering techniques



35S promoter of cauliflower mosaic virus (CaMV) and terminator is **nopaline synthase (NOS)** gene of *Agrobacterium tumefaciens*.



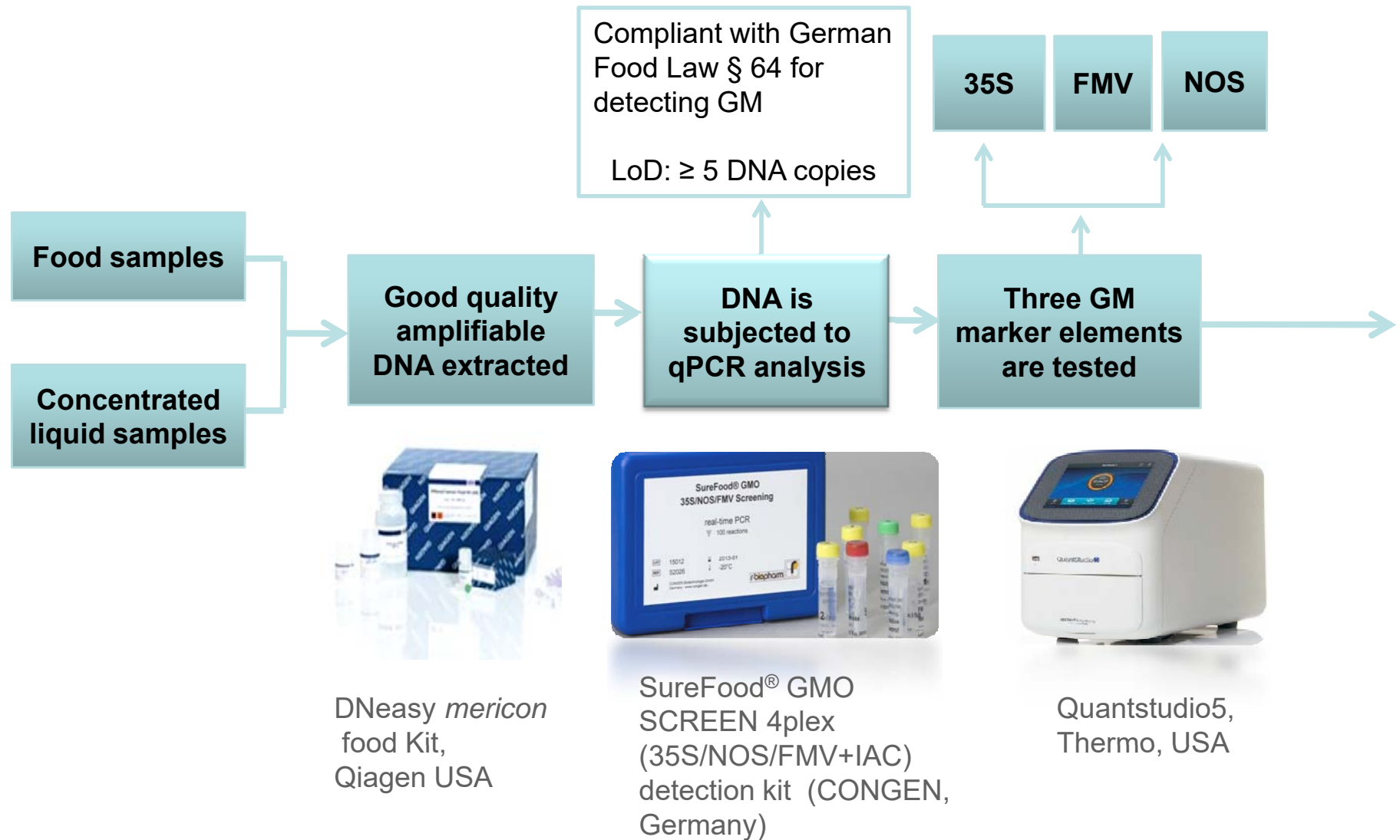
WHAT WE TESTED?





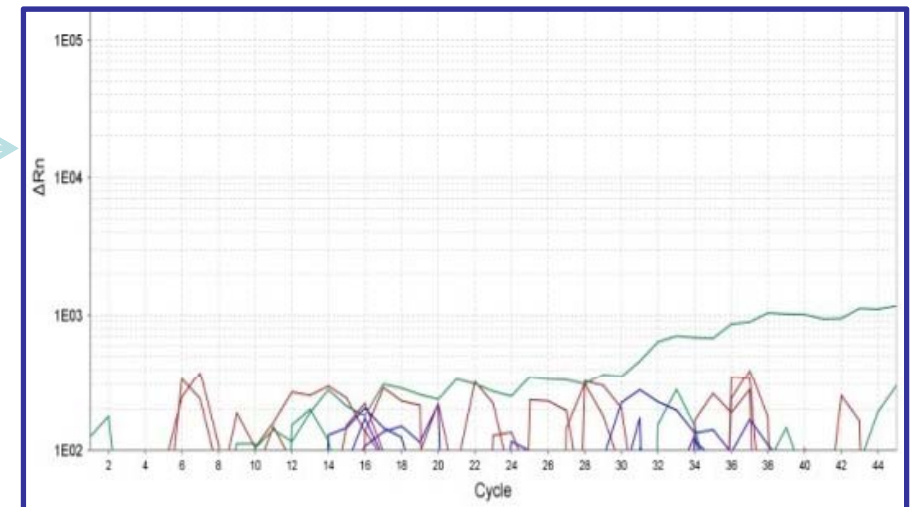
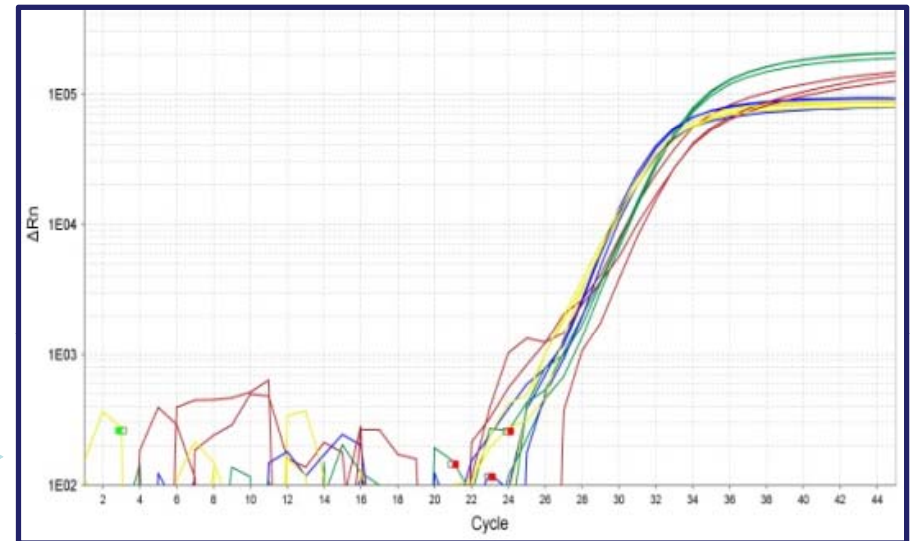
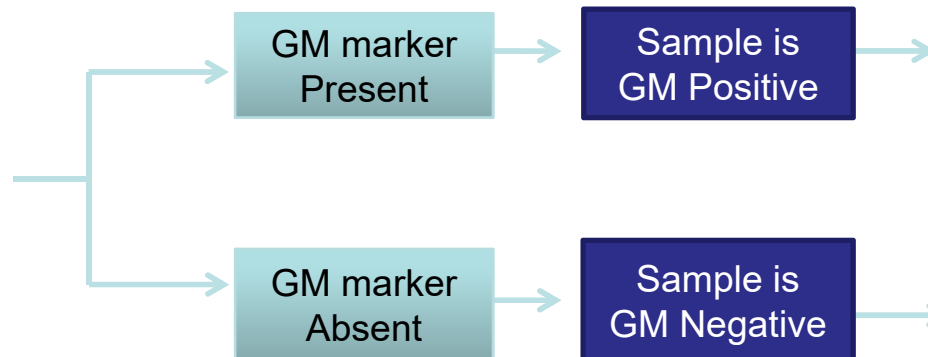
METHOD:

DNA Extraction and qPCR analysis



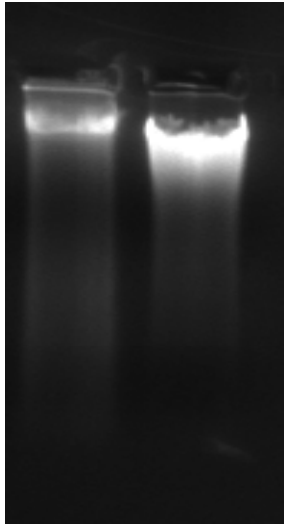


qPCR Results

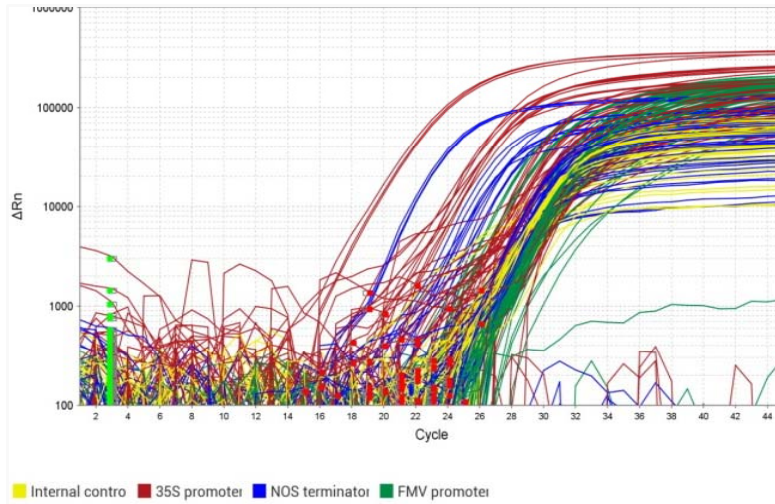




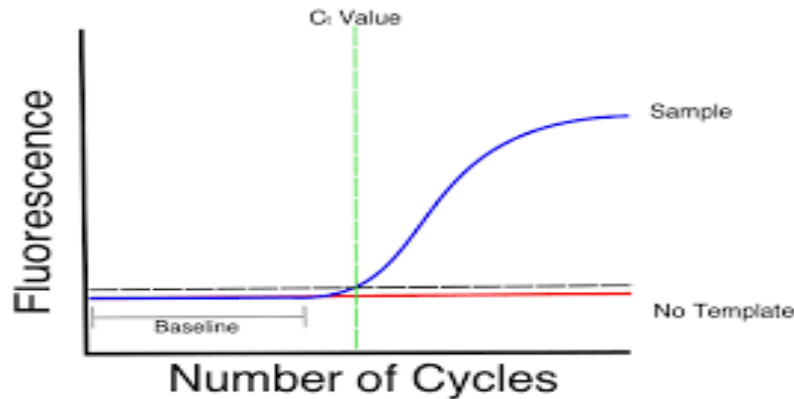
RESULT ANALYSIS



1. DNA isolated and checked on 1% ethidium bromide-containing agarose gel



2. qPCR amplification plots obtained for GM positive samples



Samples	GM targets	Ct Values
Canola oil (Hudson)	35S promoter	26.76
	NOS promoter	26.56
	FMV promoter	29.51
Cotton seed oil (Ankur)	35S promoter	27.24
	NOS promoter	26.66
	FMV promoter	29.58
Packaged foods (Corn puffs)	35S promoter	28.07
	NOS promoter	26.78
	FMV promoter	29.68
Packaged foods (Froot Loops)	35S promoter	20.77
	NOS promoter	22.49
	FMV promoter	26.26
Infant food (Similac Isomil)	35S promoter	29.23
	NOS promoter	27.42
	FMV promoter	29.87
Cotton seed (positive control)	35S promoter	24.96
	NOS promoter	25.69
	FMV promoter	29.43

3. Ct values for positive samples are obtained



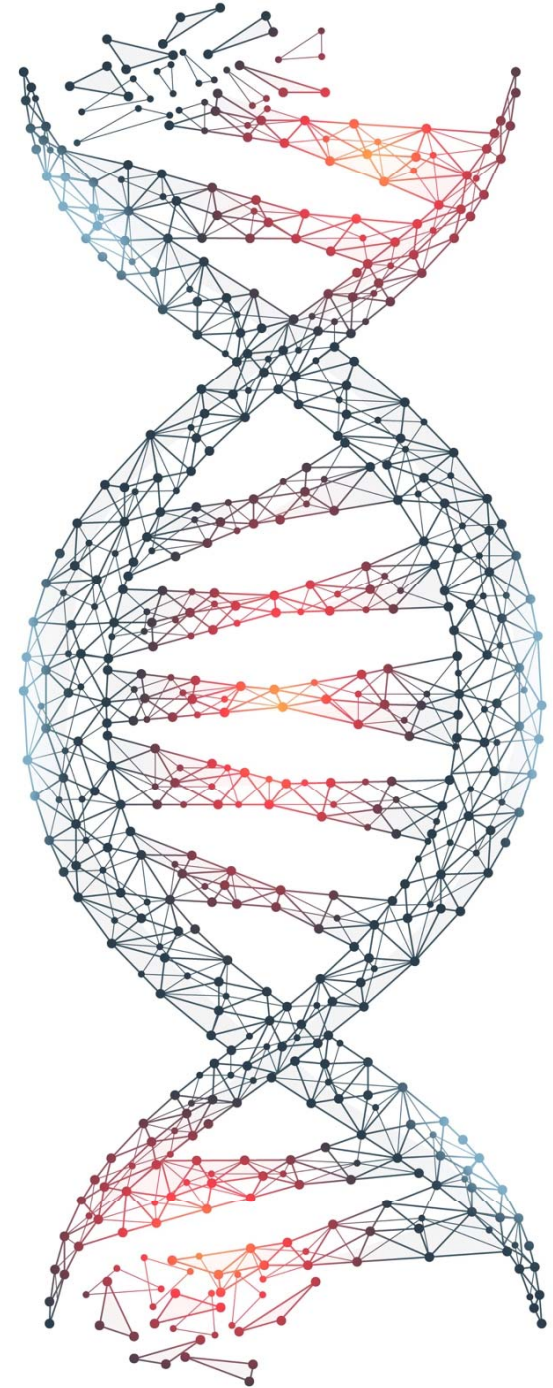
CONCLUSION

- DNA-based qPCR method is a reliable method for screening GM markers in processed food samples, which helps to identify GM food
- Our study using qPCR shows that GM foods (imported and domestically-manufactured) exist in the Indian market



RESULTS & ANALYSIS OF THE PML STUDY

**Chandra Bhushan
Deputy Director General, CSE**





WHY THIS STUDY?

There were reports about availability of illegal GM crops being grown and GM food products being sold in India.

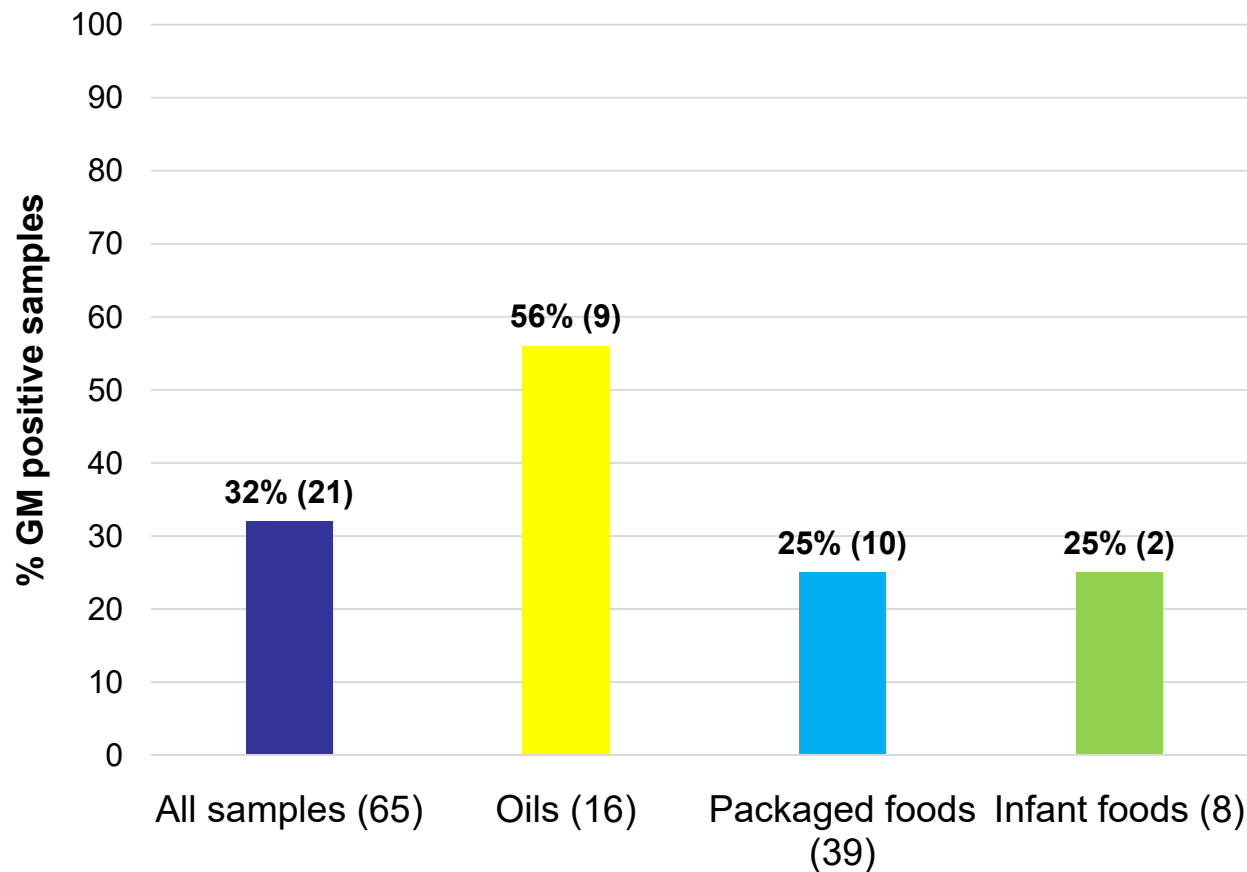
We decided to do a reality check by testing processed foods since many of these are based on common GM crops (soya, corn, canola, cotton etc.) grown in different parts of the world.



Found GM-positive foods across different categories

– all of them not approved by GEAC or FSSAI

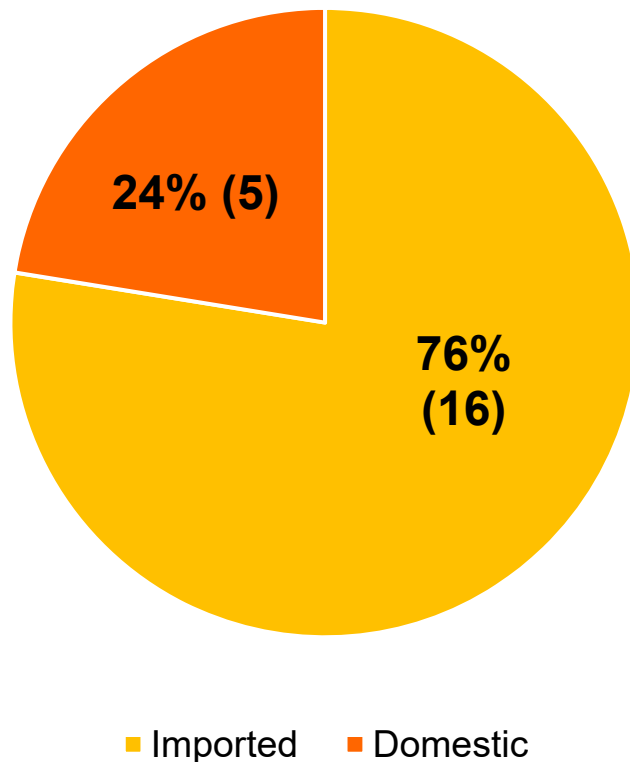
- Overall, 32% samples are GM-positive.
- 65% of these did not label use of GM ingredients, 15% mislabeled, 20% labelled 'produced from Genetic engineering'.





About **80%** of GM-positive samples were imported

GM positive samples



Imported GM-positive samples

- 46% of total imported samples
- Canola oils; packaged foods like corn based syrups, breakfast cereals, tofu, sweet corn, popcorns, croutons toast bread & corn snacks; and infant foods
- USA, Canada, the Netherlands, Thailand, UAE
- 9/16 did not mention GM on labels; 3/16 claimed GM-free/Non-GM; labels of 4/16 said use of GM ingredients

Domestic GM-positive samples

- 17% of domestic samples
- Cottonseed oils (includes 1 crude cottonseed oil)
- No mention of GM on the label



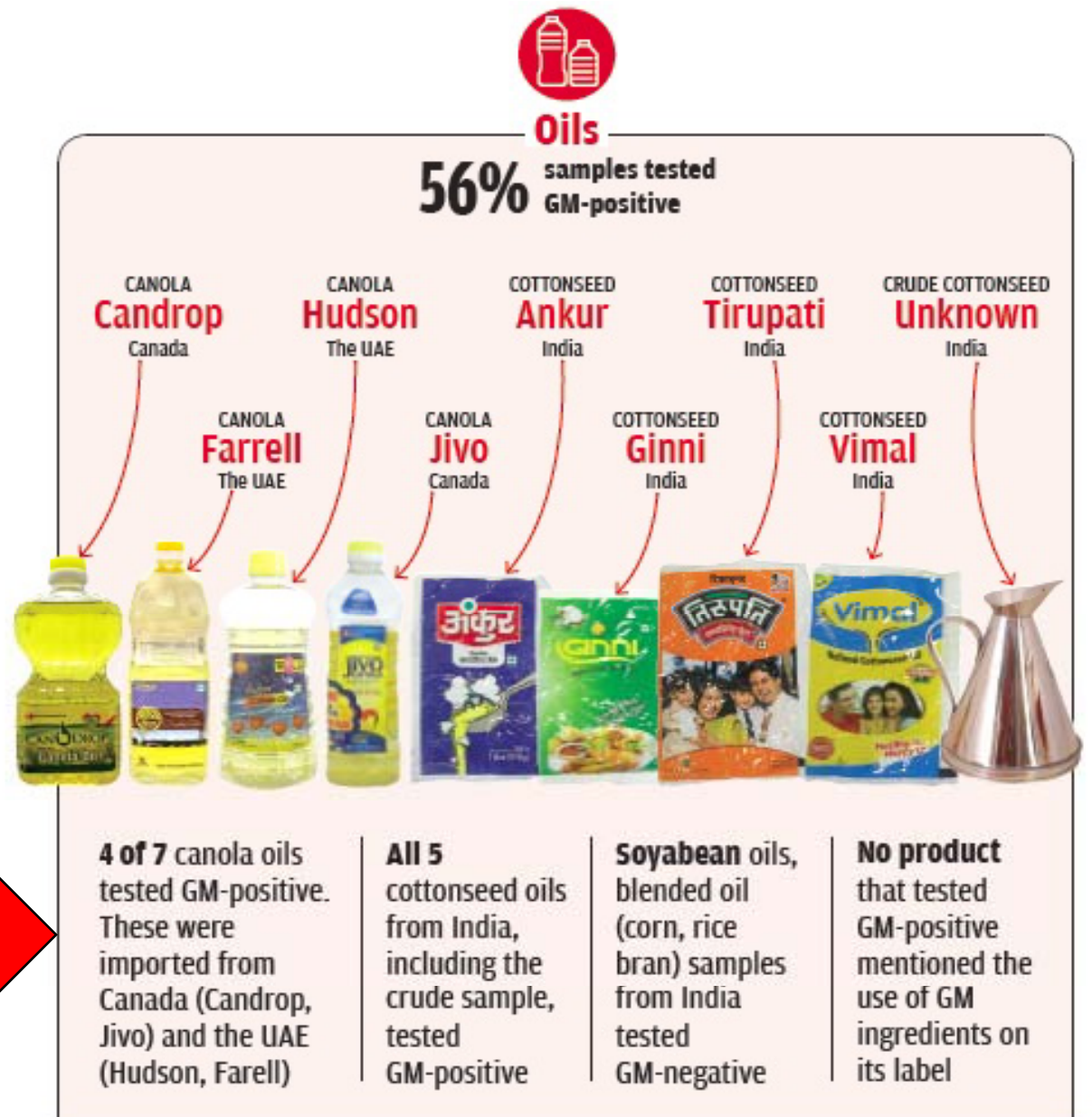
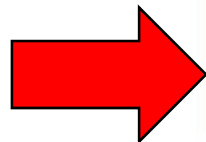
56% (9/16) of oil samples were GM-positive

Importers

- Farrell: Jindal Retail (India) Pvt Ltd
- Hudson: marketed by Dalmia Continental Pvt Ltd
- Jivo: Jivo Wellness Pvt Ltd
- Candrop: Century Edible Cooking Oils Pvt Ltd

False claim by 'Candrop' Canola oil

'GMO free' on label;
found to be **GM-positive**





26% (10/39) packaged food samples were GM-positive

- 'Froot Loops' from **Kellogg's**
- 'Crispy corn snacks' from Bugles – distributed by **General Mills** Inc, USA
- 'Butter and Garlic Croutons' – distributed by **General Mills** Sales Inc, USA,
- 'Corn puffs' from Trix – distributed by **General Mills** Sales Inc, USA,
- 'Original syrup' from Aunt **Jemima** – distributed by **Quaker Oats** in the US
- 'Dark corn syrup' from **Karo**, US.
- Imported by Newage Gourmet Foods, Bajoria Foods Pvt Ltd etc.

False claims

Two product -- Mori-Nu tofu and 'PromPlus sweet whole kernel corn' - 'Non-GMO'



Packaged foods

25% samples tested GM-positive



About 50% imported samples tested GM-positive including 8 ready-to-cook products

9 of the 10 GM-positive products were imported from USA. These include Kellogg's fruit loops, American Garden popcorn and Trix Corn Puffs

Labels on 2 of the 10 GM-positive products claimed no use of GM ingredients; labels of 4 mentioned using GM ingredients; and, 4 did not say anything

No Indian packaged food sample tested GM-positive





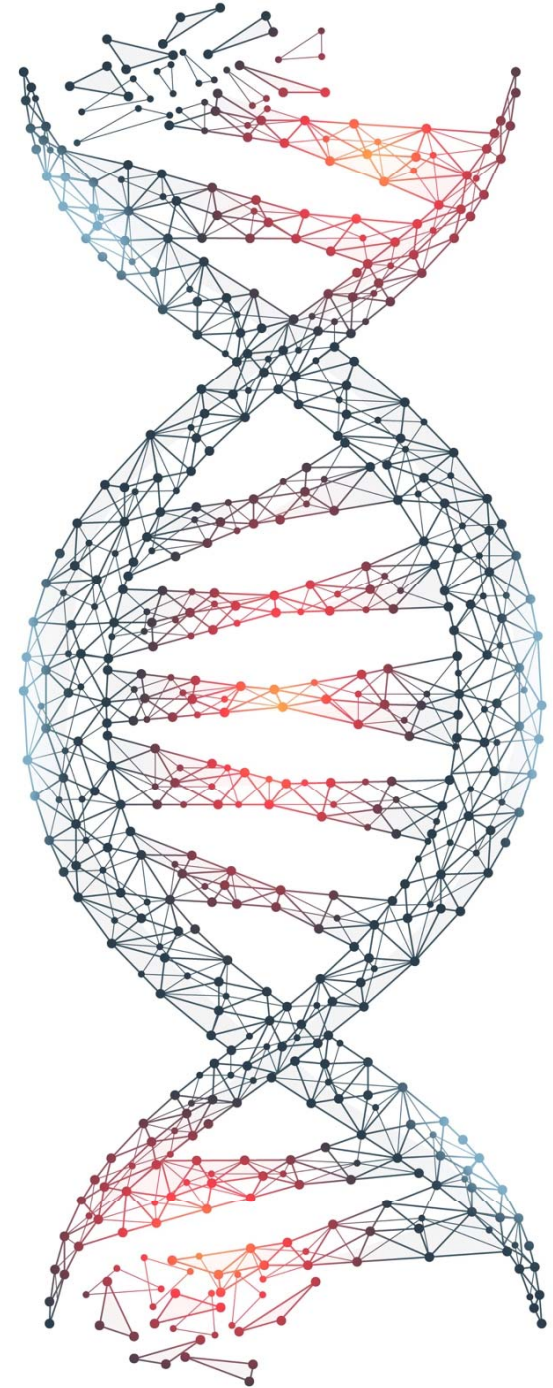
25% (2/8) infant food samples GM-positive

- Imported by Abbott Healthcare Pvt
- Similac Isomil: lactose-free infant milk-substitute soy infant formula, imported from Netherlands
- Similac Alimentum: hypoallergenic infant formula, imported from the US
- No mention of GM on the label.
- Civil society groups have been urging Abbott to remove GMOs from infant foods as long term safety of GMOs is unknown.
- **Abbott now sells Non-GMO infant formula in the US**





HEALTH AND ENVIRONMENTAL CONCERNS





A DIVIDED WORLD

- Opinion on health, safety and environmental impacts of GMOs is divided.
- Large number of scientific papers say that GMOs are safe; equally large numbers say that they are unsafe and have major concerns
- USA, Brazil, Argentina, Canada etc. have allowed large scale cultivation
- Europe, China, India etc. have allowed limited number of crops based on precautionary principle.
- But all have a system to check health, safety and environmental impacts of GMOs before they are introduced in the environment
- All have a system to approve or reject imports and sales of GM food products



Health and safety assessment of GM food before approval

- The Indian Council of Medical Research (ICMR) has published *Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, (2008, updated 2012)*
- Parameters typically to be considered for risk assessment of GM foods before approval
 - Toxicity—acute, sub-chronic and chronic
 - Allergenicity: cross reaction with other allergens or new unknown GM proteins
 - Nutritional effects: if GM DNA insertion modifies nutritional content
 - Stability of inserted gene: avoid unintended escape to gut bacteria or body cells. **Particularly relevant if antibiotic resistance genes. AMR is a huge global health threat.**
 - Unintended effects: new or changed patterns of metabolites resulting from gene insertion



STATUS CHECK: Health and safety assessment of GM foods in India

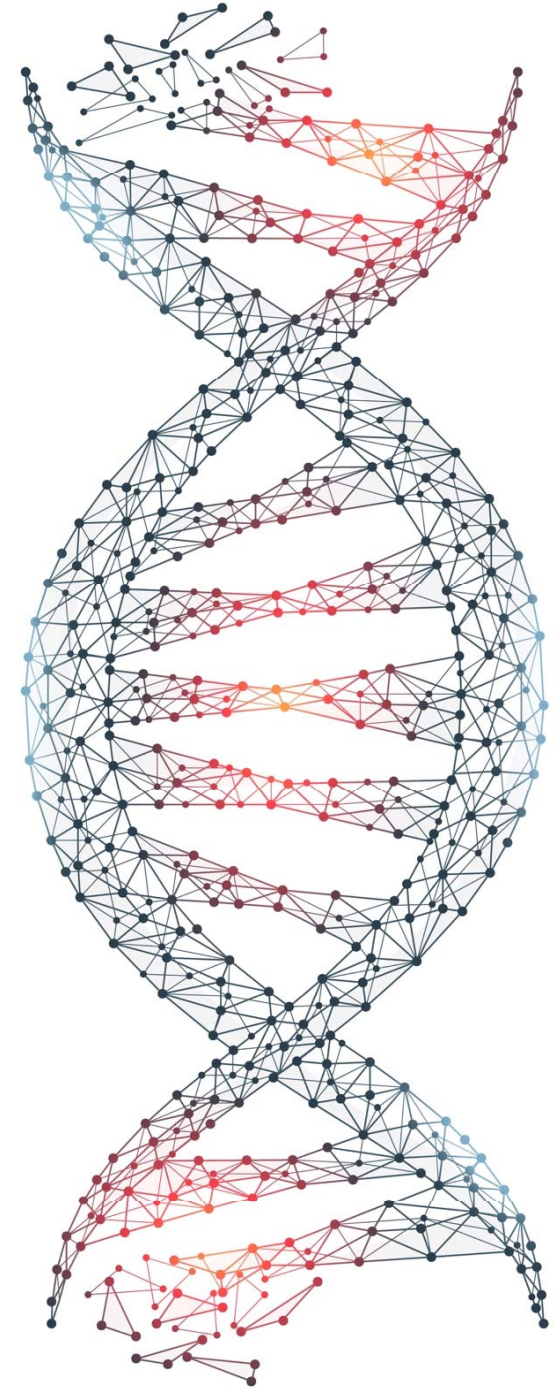
A Parliamentary Committee Report of December 2017, noted the following concerns regarding safety of GM crops on human health:

- No India-specific study: own population, climate and environment
- Long-term effects on human health not studied
- Department of Health Research has taken no action to examine impact of GM crops
- Not been scientifically proven that GM crops have no adverse impacts on human health
- Very late in the day for FSSAI to take decision to label imported GM foods
- Strongly recommended labelling on GM foods to be done with immediate effect
- **Bottom-line:** Our scientific and regulatory agencies are failing us on GMOs



GM POLICY FRAMEWORK IN INDIA

**Gaps in policy and
implementation**





CRACKS IN THE SYSTEM: GM food approval and labelling

- 1989:** GEAC (Genetic Engineering Appraisal Committee) approval made mandatory for manufacturing, selling or importing food containing GM (1989 Rules, under EPA).
- 2006:** Food Safety and Standards Act, 2006 enacted; **section 22 prohibits GM food unless approved under the Act or regulations under it**
- 2006:** Foreign Trade (Development and Regulation) Act, 1992 mandates prior permission and declaration of GM food while importing; penal action in case of violation
- 2007:** Notification issued to amend the 1989 EPA Rules to exclude processed food from the purview of the GEAC and move to FSSAI. Notification kept in abeyance till 2016
- 2007:** MoHFW wrote to MoEF&CC - continue regulating processed foods until FSSAI ready to do it scientifically.



CRACKS IN THE SYSTEM: GM food approval and labelling

2013: The Legal Metrology (Packaged Commodity) Rules, 2011 **mandate that every package containing GM food shall, at the top of its principal display panel, bear the words 'GM'**

2017: GEAC admitted a vacuum in the law w.r.t. GM processed foods as it is legally out of GEAC's purview but FSSAI has not started regulating

2018: FSSAI seeks to make labelling of GM food mandatory; issues draft (labelling and display) regulation



Who is responsible for regulating GM foods in India?

Section 3(1)(j), FSS Act, 2006: Definition of food includes GM food:

“Food means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes genetically modified or engineered food or food containing such ingredients ...”

Section 22, FSS Act, 2006: prohibits GM food until approved:

“Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food

.....except as provided under this Act and regulations made thereunder”

FSSAI is the key agency for approval and regulation of manufacture, distribution, sales or import of GM food



UNION HEALTH MINISTER AND FSSAI CONFIRM: GM food not allowed in India as FSSAI has not approved any GM food

In February, 2018, Health Minister, stated in Lok Sabha as follows (relevant text):

“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.”

Affidavit filed by FSSAI in Supreme Court of India (on May 24, 2017), wherein it was stated that:

“The Central government has not notified any regulation under Section 22 of the Food Safety and Standards Act in regard to (sic) the manufacture, distribution, sale and import of GM foods. Hence, GM foods are not allowed in the country and neither can be regulated till such notification is issued.”

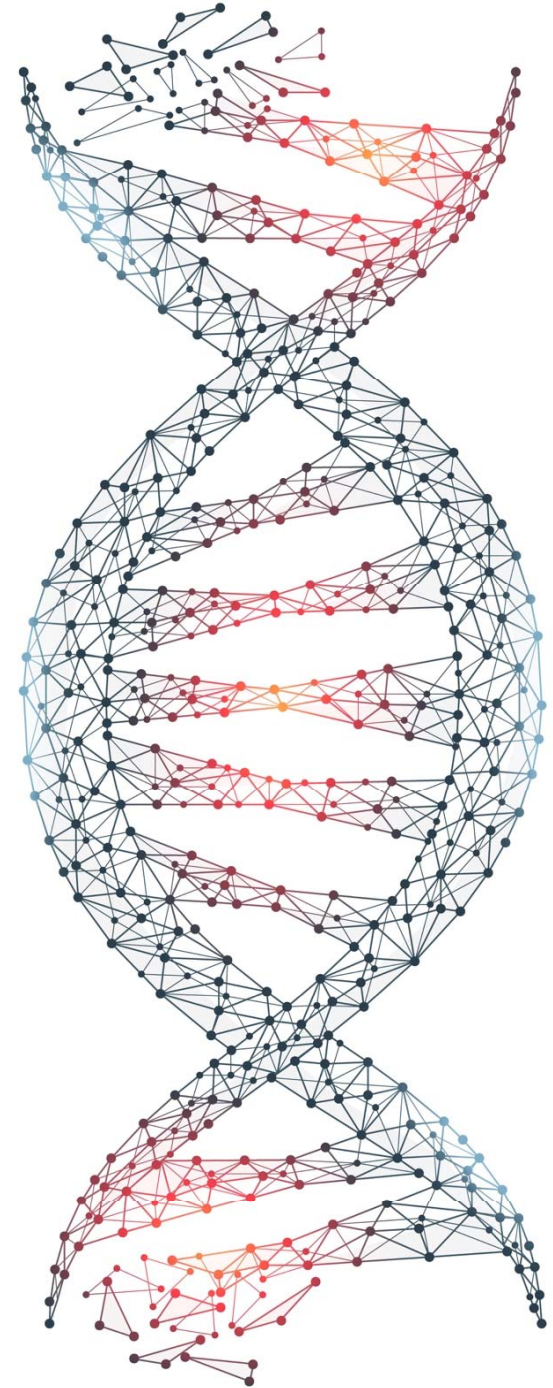


GOVERNMENT HAS TURNED A BLIND-EYE

- FSSAI approves cottonseed oil in India and also permits its use in vanaspati; **but does not considers that most of the cottonseed oil being derived from GM cotton. Even today, FSSAI has not given specific approval for cottonseed oil extracted from GM cotton**
- FSSAI approved import of 95 specialty foods—foods for special dietary needs—for inborn errors of metabolism and hypoallergenic conditions (through two orders in June and Dec 2017), **but does not considers GM**; CSE study found a GM-positive baby food products
- 65% of the GM-positive products (domestic and imported) in the CSE study did not mention the use of GM ingredients, whereas the Rule 6(7) of Legal Metrology (Packaged Commodities) Rules, 2011 states that every package containing GM foods shall bear at the top of its principal display panel the letters 'GM'.
- Products with labels claiming “contains GM” or similar claims, freely available in the market in Delhi-NCR. NGOs have filed written complaint to FSSAI. But FSSAI didn't investigate and take action



LABELLING OF GM FOOD





APRIL 2018:

FSSAI's proposed labelling on GM food

- India already has a GM labelling regulation under the Legal Metrology (Packaged Commodity) Rules, 2011. It clearly says that **“every package containing GM food shall, at the top of its principal display panel, bear the words ‘GM’”**.
- Now, FSSAI has proposed another labelling rules on GM food:
“All food products having total Genetically Engineered (GE) ingredients 5% or more shall be labelled. The total GE ingredients shall be of top three ingredients in terms of their percentage in the product. The labelling shall be as:

“Contains GMO/Ingredients derived from GMO”

FSSAI has ignored an existing Rule in its proposal.



VERY WEAK AND IMPRACTICAL TO IMPLEMENT: FSSAI's proposed labelling rule

- Five per cent threshold limit of exemption from GM labelling is very relaxed. Will allow GM food to enter the market legally without any approval

Importantly, it would be expensive and difficult to enforce

- Determination of weight of GM ingredient is expensive and technically challenging
 - Average cost of screening (qualitative testing) is Rs 10,000 per sample
 - Cost of quantifying a GM ingredient could be several times higher (Rs 25,000-60,000) and depends upon number of GM crops and events to be tested
 - Will require Certified reference genes for all possible GM crops. As India is not producing them, it would be very difficult to source them.
- **Bottom-line:** This labelling rule is based on self declaration by manufacturers. Will lead GM foods into the system without consumers being informed




FSSAI'S DOUBLE STANDARDS – Self-declaration for GM foods Vs. mandatory certification for organic food

- **GM foods (safety & environmental concerns)**
 - Relaxed standard -- No need to label till 5% ingredient
 - Difficult to monitor by enforcement agency
 - Relies on self-declaration by food industry
 - No symbol-based labelling; no details on placement, size and colour of text
- **Organic foods (known safe and environmentally sustainable food)**
 - Food Safety and Standards (Organic Foods) Regulations, 2017
 - Requires mandatory certification by producer/farmer before labelling 'organic':
 - Waiting time of three years before a farm can be certified organic
 - Third-party industry certification is very expensive for a small farmer; Participatory Guarantee System of the government has implementation gaps.

FSSAI inverse rule: Allow self-declaration on food with health and environmental concerns and impose mandatory certification for good food.



Mandatory labelling; threshold limit at or below 1%

Country/ region	Mandatory/ voluntary	Text to be labelled	Threshold set (for exemption from labelling)
European Union	Mandatory (GMO-free labelling voluntary)	List of ingredients must indicate <i>'genetically modified'</i> or <i>'produced from genetically modified [name of the organism]'</i>	up to 0.9 % GM DNA (per ingredient) in view of adventitious/technically unavoidable presence
Australia	Mandatory (GMO-free labelling voluntary)	Packaged food: 'genetically modified' either next to name of food or with specific GM ingredient in ingredient list Unpackaged food: information to be displayed with food	Unintentional presence of up to 1% (per ingredient by weight) of an approved GM ingredient in a non GM food
Brazil	Mandatory		Up to 1% of an approved GMO ingredient (by weight)



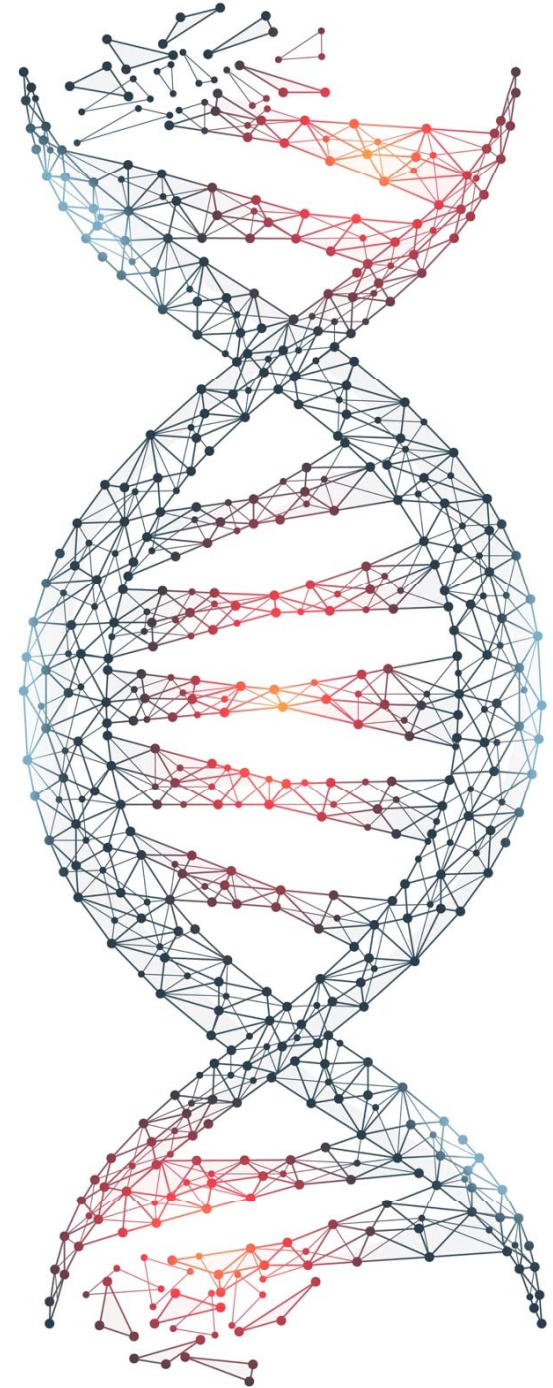


Mandatory labelling; threshold limit more than 1%; but GM crops, products and events are known

Country/ region	Mandatory/voluntary	Text to be labelled	Threshold set (for exemption from labelling)
Japan	<p>Mandatory (applicable to 33 processed food categories from 8 approved GM crops)</p> <p>Voluntary GM-free labelling allowed -33 categories not produced using 8 crops - certified as being segregated from GM products - GM DNA or protein cannot be detected</p>	GM Ingredients/GM Ingredients Not Segregated/Non-GM: as per case	Applicable to list of 33 processed food categories derived from 8 approved GM crops, less than 5% by weight of approved GM ingredients
South Korea	<p>Mandatory (for 7 approved GM crops and foods For other crops/ products, GM-free claims not allowed</p>	On principal display or ingredients panel using stickers, printed label/stamp, font size 12 points	up to 3% unintentional presence of approved GM components in non-GMO ingredient



CSE RECOMMENDATIONS





CSE RECOMMENDATIONS

for FSSAI (1)

- **Prosecute companies and traders for bringing illegal GM products in the market**
 - FSSAI must identify all illegal GM foods
 - Legal action against concerned companies and traders
- **Set up a stringent system for approving GM food products**
 - Safety assessment of GM food products
 - Case-to-case basis
 - No reliance only on manufacturer data or short-term or poor design studies
 - Safety results in the public domain



CSE RECOMMENDATIONS

for FSSAI (2)

Enact strict GM labelling based on the existing laws

- **Definition of GM food under FSS Act 2006:** “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”
- **The Legal Metrology (Packaged Commodity) Rules, 2011:** Every package containing GM food shall, at the top of its principal display panel, bear the words ‘GM’
- From the above it is clear that FSSAI’s proposed rule that says no need to label till 5% ingredient, **is in contravention of the existing laws.**
- Therefore, the correct labelling regulation in India should be: **label all products if they have used GM ingredients, even if they do not contain GM genes.**



CSE RECOMMENDATIONS

for FSSAI (3)

Set-up practical system to enforce this law

- Adopt qualitative screening methods like qPCR as an enforcement tool – this is affordable and doable
- For regulation purpose, allow 1% GM DNA as inadvertent contamination
- Onus on manufacturer to prove inadvertent contamination

Consumer friendly approach to labelling

- Symbol-based 'GM' label on front-of-pack
- Details of the GM ingredient to be provided on label

Set up laboratories for testing GM foods

- Screen all foods for GM with qPCR-based methods for effective monitoring and enforcement to curb illegal GM foods in Indian markets



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