

Voluntary Report – Voluntary - Public Distribution

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Report Name: India's FSSAI Proposes New Regulations for Genetically Modified or Engineered Foods

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report

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Report Highlights:

On November 15, 2021, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued draft regulations for Genetically Modified Organisms or Genetically Engineered Organisms, or Living Modified Organisms intended for direct use as food or for processing. The draft regulation states that “no person shall manufacture, store, distribute, sell or import in India, any food or food ingredient derived from Genetically Modified Organisms, except with the prior approval of the Food Authority. World Trade Organization (WTO) members are invited to comment on the proposed draft amendment and the timeline to provide comments is 60-days from the date of notification on the WTO website.

DISCLAIMER: The information contained in this report was retrieved from the Food Safety and Standards Authority of India's (FSSAI) website <http://www.fssai.gov.in>. The U.S. Embassy in New Delhi – Foreign Agricultural Service (FAS) Office of Agricultural Affairs (OAA), USDA and/or the U.S. Government make no claim of accuracy or authenticity. The Government of India has not officially endorsed this report. Import approval for any product is subject to local rules and regulations as interpreted by Indian officials at the time of product entry. [Note: Use Google Chrome to access the links that do not open in Internet Explorer. Indian host sites will geo-block site access on a rolling basis].

GENERAL INFORMATION

On November 15, 2021, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued Notification F.No.1/Standards/GM Food regulation/FSSAI/2018 for the proposed draft Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021 (see, Appendix I). The notification was published in the Gazette of India (official gazette) on November 17, 2021. All food products having more than 1% genetically modified (GM) ingredients should be labeled as “Contains Genetically Modified Organisms/Ingredients derived from GMO.”

The FSSAI draft regulations define:

- (i) Genetically modified or engineered (GE) foods as 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.
- (ii) Genetically modified organisms (GMOs)/genetically engineered organisms/living modified organisms (LMOs) as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

The draft regulations also cover the following topics:

- Prior approval for the manufacture, storage, distribution, sale, and import, etc., of genetically modified food products.
- Procedure for granting of prior approval.
- Food laboratory for genetically modified foods testing.
- Function of foods laboratory for genetically modified foods testing.
- GM food labeling.

A Samples of Form-I: Application for Approval for Food or Food Ingredient or Processing Aid Containing LMOs and Form-II: Application for Approval of Food or Food Ingredient or Processing Aid derived from GM ingredients but not containing LMOs in the end-product, are also included in the draft regulation.

FAS New Delhi recommends that interested stakeholders thoroughly read the full text of the draft regulations available at: https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_GM_Food_17_11_2021.pdf.) and the comments received by the FSSAI on the draft regulation during inter-ministerial consultation at: https://fssai.gov.in/upload/uploadfiles/files/Comments_Interministerial_Consultation.pdf, before providing

comments on them. World Trade Organization (WTO) members are invited to comment on the proposed draft amendment and the timeline to provide comments is 60-days from the date of notification on the WTO website.

Comments should be sent to:

The Chief Executive Officer
Food Safety and Standards Authority of India
3rd Floor, Food and Drug Administration Bhawan, Kotla Road
New Delhi – 110002
Email: spstbt.enqpt@fssai.gov.in

Details of Draft Regulation:

Publication date on the FSSAI website: November 17, 2021

Date of Implementation: To be determined.

Final Date for Comments: 60-days from the date of notification on the WTO website.

Products Affected: All food and food ingredients containing genetically modified or engineered organisms.

APPENDIX I: DRAFT FOOD SAFETY AND STANDARDS (GENETICALLY MODIFIED OR ENGINEERED FOODS) REGULATIONS, 2021

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

NOTIFICATION

New Delhi, the 15th November, 2021

F. No. 1/Standards/GM Food regulation/FSSAI/2018.—The following draft regulations, which the Food Safety and Standards Authority of India (FSSAI) proposes to make with the previous approval of the Central Government, in exercise of powers conferred by clause (v) of sub-section (2) of section 92 read with sub-section (2) of section 22 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby published as required under sub-section (1) of section 92 of the said Act, for the information of all persons likely to be affected thereby and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of a period of sixty days from the date on which the copies of the Official Gazette containing this notification are made available to the public;

Comments already received so far during inter-ministerial consultation have been examined and are available at https://fssai.gov.in/upload/uploadfiles/files/Comments_Interministerial_Consultation.pdf.

Further objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi – 110 002 or sent on email at regulation@fssai.gov.in;

Objections and suggestions, which may be received from any person with respect to the said draft regulations before the expiry of the period so specified, shall be considered by the Food Authority.

Draft Regulations

CHAPTER I

General

1. Short title and commencement- (1) These regulations may be called the Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021.

(2) They shall apply to-

- (a) Genetically Modified Organisms (GMOs) or Genetically Engineered Organisms (GEOs) or Living Modified Organisms (LMOs) intended for direct use as food or for processing.
- (b) Food or Processed food containing Genetically Modified ingredients produced from but not containing LMOs or GEOs or GMOs.

(3) They shall come into force from the date of their publication in the Official Gazette.

2. Definitions- (1) In these regulations, unless the context otherwise requires: -

- (a) “Act” means the Food Safety and Standards Act, 2006 (34 of 2006);
- (b) “Food Authority” means the Food Safety and Standards Authority of India established under section 4 of the Food Safety and Standards Act, 2006;
- (c) GEAC means Genetic Engineering Appraisal Committee under Ministry of Environment, Forest and Climate Change;

- (d) Genetic Engineering: means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. or it shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;
- (e) “Genetically Modified or Engineered 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;
- (f) “Genetically Modified Organisms/ Genetically Engineered Organisms / Living Modified Organisms” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; and
- (g) “Foods Laboratory for Genetically Modified Foods Testing” means any food laboratory defined under the Act approved by Food Authority specific for the purpose of testing of Genetically Modified Foods.

(2) Words and expressions used herein and not defined in the regulation but defined in the Act shall have the meanings assigned to them in the Act.

3. Prior Approval for manufacture, storage, distribution, sale and import etc.-

(1) No person shall manufacture, store, distribute, sell or import in the country any food or food ingredient, as the case may be, derived from Genetically Modified Organisms, except with the prior approval of the Food Authority.

(2) The provisions of these regulations are in addition to, and not in derogation of, any other rules or regulations made under the act.

4. Procedure for grant of prior approval (1) In case a Genetically Modified or Engineered Food contains any Living Modified Organisms (LMOs), after taking prior approval from GEAC for Environmental safety, the application for the approval of the Food Authority may be submitted in Form-I along with the documents and fees as specified by the Food Authority from time to time.

(2) In case a Genetically Modified or Engineered Food does not contain any LMOs, the application for the approval of the Food Authority may be submitted directly in Form-II along with the documents and fees as specified by the Food Authority from time to time.

(3) The Food Authority shall scrutinize the application and information provided by the applicant.

(4) The Food Authority may direct the applicant to submit additional supporting documents, data or clarifications, if required.

(5) The Food Authority may either grant approval or reject the application on the basis of the safety assessment of the article of food or food ingredient of processing aid.

(6) The food business operator shall, after grant of approval apply for license as per the procedure specified in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

(7) A food business operator, who is aggrieved by the decision of the Food Authority, may file an appeal before the Chairperson.

(8) The Food Authority may, for reasons to be recorded in writing, suspend or revoke any approval granted to any food business operator.

(9) Post approval, if a food business operator has reason to believe that the Genetically Modified or Engineered Food poses any risk to health, he shall immediately suspend the manufacture, import, sale, or distribution of such article of food and take steps to recall the same in accordance with the provisions of the Food Safety and Standards (Food Recall) Regulations, 2017.

(10) Food Safety Officers and Designated Officers shall immediately inform the Food Authority of any complaint received regarding safety of any product approved by the Food Authority under these regulations.

(11) Once a Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms having unique identification Code provided by Biosafety Clearing House, Organisation for Economic Co-operation and Development etc, is approved by FSSAI, approval for the same will not be required for any other Food Business Operator. Approval will also not be required if it is used as an ingredient in any product.

(12) Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organism shall not be used as an ingredient in any infant food.

5. Foods Laboratory for Genetically Modified Foods Testing - Any food laboratory notified in accordance with section 43 of the Food Safety and Standards Act, 2006 may be designated for Genetically Modified Foods Testing having the following pre-requisite:

(1) The laboratory shall have a designated GM food testing area that should be well segregated from the general laboratory working area and should have four physically separate and contained areas for Reagent and Sample preparation, DNA and Protein extraction, Product Analysis, and Data analysis and storage with air conditioning/ventilation. Airflows should be maintained within the Genetically Modified food testing area.

(2) The laboratory shall have instruments for detection of DNA/ RNA by qRT-PCR, Protein by ELISA and Western blotting and GM organism by Fluorescent microscopy.

(3) The laboratory shall be able to assess multiple batches of samples.

(4) The GM food testing laboratory staff shall be well versed with these regulations and proficient with techniques related to molecular biology, protein biology and food testing.

6. Function of Foods Laboratory for Genetically Modified Foods Testing - In addition to the functions entrusted to Food Laboratory under the Act, the notified laboratory designated for Genetically Modified Foods Testing shall carry out the following functions, namely:

- (a) Analyse samples of food sent by any officer or organization authorized by the Food Authority for the purpose of Genetically Modified testing and submission of the certificate of analysis to the authorities concerned. Each sample of Genetically Modified Foods shall be tested in triplicate.
- (b) Ensure that the laboratory follows the scientific protocols and practices as laid down by Food Authority from time to time.
- (c) Identify and clearly establish Standard Operating Procedures (SOPs) for every step of the workflow for the Genetically Modified testing procedures.
- (d) Maintain high standards of accuracy, reliability and credibility in the operation of the laboratory and achieving and maintaining the required levels of accreditation and reliability.
- (e) Lay down mechanism for ensuring that personnel of the laboratory adhere to high professional standards and discipline to ensure safety and security of GM food materials received for analysis and report.
- (f) Maintain hard and soft data of the results and reports for a definite period of time unless specified otherwise by Food Authority as and when required.

7. GM Food Labelling- All food products having individual Genetically Engineered (GE) ingredient 1% or more shall be labelled. The labelling shall be as:

“Contains GMO/Ingredients derived from GMO”

FORM – I

(See regulation 4)

Application for Approval for food or food ingredient or processing aid containing Living Modified Organism (LMOs)

Instructions:

- *Fields marked with asterisk are applicable only in case of import.*
- *Scanned enclosures shall not be acknowledged except for page(s) which bear signature(s) on it.*

1. Applicant and Organization details

- (1) Name of the Applicant:
- (2) Designation:
- (3) Name of the Organization:
- (4) Contact Address:
- (5) Telephone No.:
- (6) Mobile No.:
- (7) E-mail:

2. Description of Items applied for approval

- (1) Name of the product:
- (2) Intended use:
- (3) Purpose of import*:
- (4) Quantity per year of the product to be imported*:
- (5) Details of earlier import, if any*
 - (a) Whether the proposed GMOs/ LMOs was imported earlier: Yes No
If yes, provide the copy of relevant permit issued previously and quantities imported.
 - (b) Statement of utilization on the earlier GMOs/LMOs and products thereof imported:

3. Shipment Details*

- (1) Port of Loading/Shipment:
- (2) Port of Discharge in India:

4. Source of GMOs/LMOs proposed to be imported: *

- (1) Name of the Agency:
- (2) Contact person's name:
- (3) Designation:
- (4) Address:
- (5) Contact No.:
- (6) Email:

5. Mode of Transport:

Rail Road Air Ship

6. End User Details: (Applicable only under section 2(2) intended use indicated as processing)

- (1) Information on End user(s)
- (2) Name & Designation:
- (3) Organization:
- (4) Contact Address:
- (5) Telephone No.:
- (6) Mobile No.:
- (7) E-mail:
- (8) Purpose for which the end product will be utilized:
- (9) Manufacturing/Business/ other activity of the end user:

7. Pre-requisites for safety assessment of GM food to be provided by applicant:

- (1) Document of approval from GEAC
- (2) A complete dossier as submitted to and approved by the regulatory agency of the exporting country or GEAC.
- (3) Three years' data of the safe use of the GMOs derived food in the country of origin*
- (4) Evidence for export of the GMOs/LMOs for food purposes with the information about the trade volume and name of the importing country(ies)*.

8. Biosafety Description of items applied for approval

- (1) The biological characteristics including Binomial name, common name, mode(s) of propagation, and pollen behaviour of the recipient/host organism host(s) carrying the vector(s)/target gene(s).
- (2) Name and identity of the GMO(s)/LMO(s) including identification code or event name for each transgenic event incorporated in the genotype.
- (3) Details of the GE trait including information to demonstrate the effects of genetic engineering.
- (4) Whether the genetic engineering leads to change in the phenotype of the GMOs/LMOs compared to the unmodified organism of the same genotype? If yes, provide details.
- (5) Brief description of the transformation method followed for each event and method of stacking (if applicable).
- (6) Details of gene construct(s):
 - (a) Name of transformation vector(s) and gene construct(s).
 - (b) Gene Construct(s) map showing base pair positions of all genetic elements and important unique restriction sites.
 - (c) Annotated complete DNA sequence of the integrated gene construct along with flanking region (from RB to LB) in a relevant (editable) format (e.g., .txt, .fasta, .fsa, .doc).
 - (d) Binomial name and common name of source organism for each genetic element of present in gene construct(s).
 - (e) Briefly describe any modification(s) made in native DNA sequence (from the source organism) of the incorporated genetic elements.
 - (f) Whether the introduced DNA contains any sequences derived from known human, animal or plant pathogens? If yes, provide details.
 - (g) Whether any of the source organism is a known source of allergen(s) and/or toxin(s)? If yes, provide details.
 - (h) ORF analysis of integrated gene construct(s) and flanking DNA sequences on all six reading frames.
 - (i) Amino acid sequence of expressed ORFs/proteins as data files in a relevant format (e.g., .txt, .fasta, .fsa, .doc).
 - (j) Bioinformatics analysis of each expressed ORF(s)/protein(s) to detect homology with allergens, anti-nutrients and toxic proteins.
 - (k) Whether the protein(s) encoded by the introduced DNA known for any post-translational modification in source organism? If yes, provide details.
- (7) Characterization of Event(s):
 - (a) Copy number analysis of the inserted gene construct(s).
 - (b) Whether the vector backbone sequence(s) present in the selected event? If yes, provide details of the vector sequence present in the host genome. If no, provide confirmatory data ascertaining the absence of vector backbone sequence(s).

- (c) Briefly describe any target site rearrangement(s), addition(s), or deletion(s) occurred at the gene construct insertion locus in host organism's genome DNA in compare the type pre-insertion locus.
 - (d) Briefly describe rearrangement(s) (e.g., addition(s), deletion(s), duplication, truncation etc.) in the integrated gene construct(s) in comparison to that of in the transformation vector(s).
 - (e) Describe genomic (chromosomal) location of the integration site and flanking region endogenous gene(s) of the host plant.
- (8) Details of event specific experimental methods to detect the presence of the transferred gene construct(s) (and gene(s)) at 0.01% Limit of Detection (LoD 0.01) in recipient plants/ progeny of recipient plants.
- (9) Expression:
- (a) Details on each expressed RNA that includes:
 - (i) Size & nucleotide sequence of the expressed RNA(s)
 - (ii) Type of expression (constitutive, tissue specific, inducible etc.)
 - (iii) Relative expression level of each expressed RNA in each major tissue/organ at key developmental stages and the detection protocol for the RNA(s) which does not translate in to peptide.
 - (b) Background information on history of use, allergenicity, and toxicity of the expressed transgene protein(s).
 - (c) Details on each expressed protein that includes:
 - (i) Size of the protein.
 - (ii) Type of expression (constitutive, tissue specific, inducible etc.)
 - (iii) Quantitative analysis in each major tissue/organ (including mean and maximum level protein in the imported plant part/tissue and edible portions) at key developmental stages of the GMOs/LMOs.
 - (iv) Details of the procedure followed for protein detection and detection limit of the method (in nanogram).
- (10) Whether the genetic modification intended to alter seed dormancy, viability or germination rate? If yes, provide details.
- (11) Whether the genetic modification intended to alter vegetative dispersal? If yes, provide details.
- (12) Whether the genetic modification intended to alter plant nutrient composition? If yes, provide details.
- (13) Whether any untoward results were observed in animal toxicological studies? If yes, provide details.
- (14) Whether any untoward results were observed in assessment of allergenicity of the newly expressed protein(s)? If yes, provide details.
- (15) List of gene/events approved in the same crop species for commercial production in the country of origin*.
- (16) Approved uses of the living modified organism in the country of origin*.
- (17) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- (18) Stability and Shelf Life of product.

9. Regulatory status in country of origin- In case the certificate is issued by the concerned authority of country of origin, the certificate should be endorsed/ authenticated by Indian Embassy/High Commission/Consulate in that country/Embassy of the country of origin in India *.

10. Every certificate shall be accompanied by other statutory information like manufacturing batch no., date of manufacture, date of analysis, date of release of the certificate, signatory to the certificate etc.

Declaration:

I declare that the information provided in the above format is correct and accurate to the best of my knowledge.

Applicant's signature with seal.

Date

Place

FORM – II

(See regulation 4)

Application for Approval of food or food ingredient or processing aid derived from Genetically Modified Ingredients but not containing Living Modified Organism (LMOs) in the end product

Instructions:

- *Fields marked with asterisk are applicable only in case of import.*
- *Scanned enclosures shall not be acknowledged except for page(s) which bear signature(s) on it.*

1. Applicant and Organization details

- (1) Name of the Applicant:
- (2) Designation:
- (3) Name of the Organization:
- (4) Contact Address:
- (5) Telephone No.:
- (6) Mobile No.:
- (7) E-mail:

2. Description of Items applied for approval

- (1) Name of the product:
- (2) Intended use:
- (3) Purpose of import*:
- (4) Quantity per year of the product to be imported*:
- (5) Details of earlier import, if any*
 - (a) Whether the proposed GMOs/ LMOs was imported earlier: Yes No
 - If yes, provide the copy of relevant permit issued previously and quantities imported.
 - (b) Statement of utilization on the earlier GMOs/LMOs and products thereof imported:

3. Shipment Details*

- (1) Port of Loading/Shipment:
- (2) Port of Discharge in India:

4. Source of Food or Processed food containing genetically modified ingredients proposed to be imported*:

- (1) Name of the Agency:
- (2) Contact person's name:
- (3) Designation:
- (4) Address:

(5) Contact No.:

(6) Email:

5. Mode of Transport

Rail Road Air Ship

6. Prerequisites for safety assessment of GE food to be provided by applicant:

- (1) A complete dossier as submitted and approved by the regulatory agency of the exporting country or complete dossier prepared by the applicant.
- (2) Three years' data of the safe use of the GMOs derived food in the country of origin*
- (3) Evidence for export of the GMOs/LMOs derived processed product for food purposes with the information about the trade volume and name of the importing country/ies*

7. Biosafety Description of Items applied for approval

- (1) Name and identity of the living modified organism(s) from which the product has been derived
- (2) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (3) Category of genetic modification:
- (4) Brief description of target trait:
- (5) Whether derived from living modified organism or one of the ingredients has been derived from GMOs/LMOs? Provide details.
- (6) Suggested detection and identification methods and their specificity, sensitivity and reproducibility:
- (7) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- (8) Stability and Shelf Life of product:

8. Regulatory status in country of origin. In case the certificate is issued by the concerned authority of country of origin, the certificate should be endorsed/ authenticated by Indian Embassy/High Commission/Consulate in that country/Embassy of the country of origin in India *.

9. Every certificate shall be accompanied by other statutory information like manufacturing batch no., date of manufacture, date of analysis, date of release of the certificate, signatory to the certificate etc.

Declaration:

I declare that the information provided in the above format is correct and accurate to the best of my knowledge and that the above-mentioned food does not contain GMOs/LMOs in the end product.

Applicant's signature with seal.

Date

Place

ARUN SINGHAL, Chief Executive Officer

[ADVT.-III/4/Exty./430/2021-22]

Attachments:

No Attachments.