

Voluntary Report – Voluntary - Public Distribution

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Report Name: India Proposes Draft Regulations for Genetically Modified Food for a Second Time

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report, Biotechnology and Other New Production Technologies

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Report Highlights:

On November 21, 2022, the Government of India's Food Safety and Standards Authority of India (FSSAI) notified its draft notification F.No. 1/Standards/GMO&F/Misc/FSSAI/2018 (November 18, 2022). The proposed regulation relates to Genetically Modified Organisms (GMO) intended for food use; food ingredients produced from GMOs that contain modified DNA; and food ingredients produced from GMOs that do not contain modified DNA, including ingredients/additives/processing aids derived from GMOs. The published draft regulation is yet to be notified to the World Trade Organization members for comments. The previous draft regulation on this topic notified on November 15, 2021, stands withdrawn (see, GAIN-INDIA-IN2021-0138-India's FSSAI Proposes New Regulations for Genetically Modified or Engineered Foods).

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 Foreign Agricultural Service (FAS) Office of Agricultural Affairs at the U.S. Embassy in New Delhi, 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 Edge or Explorer. Indian host sites will geo-block site access on a rolling basis].

GENERAL INFORMATION:

On November 21, 2022, the Government of India's Food Safety and Standards Authority of India (FSSAI) notified on its website draft notification F.No. 1/Standards/GMO&F/Misc/FSSAI/2018 (November 18, 2022) (see, Appendix I). The draft regulations relate to Genetically Modified Organisms (GMO) intended for food use; food ingredients produced from GMOs that contain modified DNA; and food ingredients produced from GMOs that do not contain modified DNA, including ingredients/additives/processing aids derived from GMOs.

The proposed draft regulations require mandatory prior approval from the food authority to manufacture, pack, store, sell, market or distributes or import any food or food ingredients produced from GMOs. The food business operator must apply as per the format prescribed by the food authority along with necessary documents and fees. The published draft regulation is yet to be notified to the World Trade Organization members for comments. The previous draft regulation specific to this topic notified on November 15, 2021, stands withdrawn (See: [GAIN-INDIA-IN2021-0138-India's FSSAI Proposes New Regulations for Genetically Modified or Engineered Foods](#)).

The draft regulations define the following:

- (i) Genetically modified (GM) food, meaning food and food ingredients composed of, or containing, genetically modified or genetically engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified organisms obtained through modern biotechnology.
- (ii) Genetically modified or genetically engineered organisms as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
- (iii) Modern Biotechnology as application of (i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.

The draft regulations also cover the following topics:

- Prior approval for manufacture, storage, distribution, sale and import etc., of genetically modified food products

- Procedure for granting of prior approval
- GM Food Labeling
- Requirements to comply with the provisions of other regulations made under the Food Safety Act, 2006

The full text of the FSSAI draft notification is included below and available on FSSAI's website at: https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_GM_Food_21_11_2022.pdf

APPENDIX I: DRAFT FOOD SAFETY AND STANDARDS (GENETICALLY MODIFIED FOODS) REGULATIONS, 2022

Food Safety and Standards Authority of India

NOTIFICATION

New Delhi, the 18 November, 2022

F. No. 1/Standards/GMO&F/Misc/FSSAI/2018.—The following draft regulations, which the Food Safety and Standards Authority of India proposes to make with previous approval of the Central Government, in exercise of the 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 copies of the Gazette containing this notification are made available to the public.

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 – 110002 or sent on email at regulation@fssai.gov.in

Objections or 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 Safety and Standards Authority of India.

Draft Regulations**CHAPTER I****General**

1. Short title and commencement—(1) These regulations may be called the Food Safety and Standards (Genetically Modified Foods) Regulations, 2022.

(2) They shall apply to-

- (a) Genetically Modified Organisms (GMOs) intended for food use.
- (b) Food ingredients produced from GMOs that contain modified DNA.
- (c) Food ingredients produced from GMOs that do not contain modified DNA. It includes ingredients/additives/processing aids derived from GMOs.

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

(4) They shall not apply to genome edited crops of SDN1 and SDN2 category.

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) “Approval” means a permission to manufacture or import any article of food or food ingredients produced from a GMO, intended directly or indirectly for human consumption;
- (c) “Conventional counterpart” means a similar food produced without the use of genetic modification and for which there is a well-established history of safe use;
- (d) “Food Authority” means the Food Safety and Standards Authority of India established under Section 4 of the Food Safety and Standards Act, 2006;
- (e) “GEAC” means Genetic Engineering Appraisal Committee under Ministry of Environment, Forest and Climate Change;
- (f) “Genetically Modified Food (GM-food)” means food and food ingredients composed of or containing genetically modified or genetically engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified organisms obtained through modern biotechnology;
- (g) “Genetically Modified or genetically engineered Organisms (GMO)” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
- (h) “Genetically modified organism for food use” means a GMO that may be used as food or as a source material for the production of food;
- (i) “Modern Biotechnology” means the application of: (i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection;
- (j) “Modified DNA” means DNA, which as a result of the use of modern biotechnology, is different from the DNA present in the conventional counterpart;
- (k) “Produced from GMOs” means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs.

(2) The words and expressions used herein and not defined, but defined in the Act or rules or regulations made thereunder, shall have the meaning as assigned to them in the Act, rules or regulations.

3. Prior approval for manufacture, storage, distribution, sale and import etc.—

(1) No person shall manufacture, pack, store, sell, market or otherwise distribute or import any food or food ingredient produced from GMOs, 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) The food business operator (manufacturer/importer) of a GM-food shall submit an application as per the format prescribed by the Food Authority along with necessary documents and fee to the Food Authority.

(2) If the application is for a GMO referred to as in clause (a) of sub-regulation (2) of regulation 1, clearance from Genetic Engineering Appraisal Committee (GEAC), the national competent authority for the environmental risk assessment shall be submitted to the Food Authority.

(3) If a GMO referred to as in clause (a) of sub-regulation (2) of regulation 1 is to be used as seeds or other plant-propagating material (cultivation), food business operator shall parallelly submit an application to the GEAC, Ministry of Environment Forest and Climate Change (MoEF&CC) for compliance to Rules 1989 for 'The manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells rules, 1989. The application may be submitted in the relevant Form IIB, Application for environmental approval of transgenic plants (Genetically Modified Plants) of GEAC.

(4) In order to prepare its opinion, the Food Authority shall verify that the particulars and documents submitted by the applicant are in accordance with the information sought and examine whether the food is safe for human consumption.

(5) The Food Authority may direct the applicant to submit additional supporting documents, data or clarifications, if required, within a specific time limit.

(6) In giving its decision, the Food Authority shall endeavour to respect a time limit not exceeding six months from the receipt of a valid application. Such a time limit shall be extended whenever supplementary information from the applicant as provided for in sub-regulation (4) of regulation 4 is sought.

(7) The Food Authority may either grant approval or reject the application as per the format prescribed by the Food Authority on the basis of the safety assessment of the food.

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

(9) After an approval has been issued in accordance with this Regulation, the authorised holder and the parties concerned shall comply with any conditions or restrictions which have been imposed in the approval and shall in particular make sure that products not covered by the approval are not placed on the market as food.

(10) The food business operator may file an appeal before the Chairperson of the Food Authority, within 30 days of receiving the letter of rejection.

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

(12) If a food business operator has reason to believe that the GM-food for which the approval was granted poses any risk to health, he shall immediately suspend the manufacture, import, sale, or distribution of such an article of food and take steps to recall the same under intimation to Food Authority in accordance with the provisions of the Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

(13) A GMO, with a 'Unique Identifier Nine-digit Code' of the Organisation for Economic Cooperation and Development (OECD) that is approved for food use by the Food Authority, will require no further approvals. However, if the GMO is to be used as seed or other plant-propagating material, approval is required from GEAC.

(14) GMOs as referred to in clause (a) and (b) of sub-regulation (2) of regulation 1 shall not be used as ingredients in infant foods.

5. Labelling—

(1) All food products as referred to in clause (a) and (b) of sub-regulation (2) of regulation 1 must be labelled with the words 'Contains genetically modified organisms', if the product contains one percent or more of the GM ingredient considered individually.

(2) This label must appear on the front of pack of pre-packaged products.

(3) This labelling requirement also applies to adventitious or technically unavoidable presence of GM ingredients.

(4) This labelling requirement is not applicable to GM-food products in which the modified DNA is not detectable as referred to in clause (c) of sub-regulation (2) of regulation 1.

(5) In addition, all GM-foods shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging) Regulations, 2018 and Food Safety and Standards (Labelling and Display) Regulations, 2020.

6. Requirement to comply with the provision of the other regulations made under the Act—

Without prejudice to the provisions of these regulations, all GM-foods shall comply with the relevant provisions, as applicable, under the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011. The GM-food shall also comply with relevant provisions, as applicable under the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

S GOPALAKRISHNAN, Chief Executive Officer

[ADVT.-III/4/Exty./414/2022-23]

Attachments:

No Attachments.