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FSSAI Proposes Draft Regulation on New Product Approval Procedures

Report Categories:

Sanitary/Phytosanitary/Food Safety

Food and Agricultural Import Regulations and
Standards - Narrative

Exporter Guide

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Report Highlights:

India published its draft Regulation on new product approval procedures and notified them to the World Trade Organization (WTO). Comments are invited from the WTO member countries until December 16, 2016.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the GOI and WTO websites: <http://www.fssai.gov.in/> and www.wto.org. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

On October 4, 2016, the Food Safety and Standards Authority of India (FSSAI) published its new draft Regulation called the [“Food Safety and Standards \(Approval for Non-Specified Food and Food Ingredients\) Regulations, 2016”](#). The draft Regulation outlines new product approval procedures for all food products not already covered under any preexisting Regulations under the Food Safety Act, 2006. These products have been termed by FSSAI as “non-specified food and food ingredients.”

Comments are invited from the WTO member countries on the draft Regulation and the timeline to comment expires on December 16, 2016.

The main features of the draft Regulation are noted below:

- Non-specified food products or food ingredients are defined as those products which are not allowed to be manufactured, stored, sold, distributed or imported under any other Regulation under the Food Safety Act, 2006. These products will require prior approval from FSSAI. The various categories of food products covered under this category are :
 - Novel foods or foods containing novel ingredients which do not have a history of human consumption in India;
 - Food ingredients that have a history of human consumption in India, but are not specified under and preexisting Regulations under the Food Safety Act, 2006;
 - New additives and processing aids; and
 - Foods manufactured or processed using novel technology
- The proposed Regulation includes the applications formats along with details on the supporting documentation required while applying for product approval.

Annexure I: Application for approval of non-specified food and food ingredients

Annexure II: Application for:

- Novel foods or foods containing novel ingredients or processed with the use of Novel technology
- Food ingredients with a history of human consumption in India but not specified in any Regulations under the Act
- New Additives
- Processing Aids and Enzymes
- Foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae

For additional information on the procedure and formats, interested readers may refer to the full text of the notification pasted at the end of the report or on the website of FSSAI at www.fssai.gov.in/.

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: baranip@yahoo.com

Details of Notification:

- Date of Publication on FSSAI website: October 4, 2016
- Date of Implementation: To be determined
- WTO Notification Number: G/SPS/N/IND/163
- WTO Notification Date: October 17, 2016
- Final date for comments: December 16, 2016

Agency in Charge: Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, GOI.

**Notice Calling for suggestions, views, comments etc from WTO- SPS
Committee members within a period of 60 days on the draft
Food Safety and Standards (Approval for Non-Specified Food and Food
Ingredients) Regulations, 2016.**

1 Short title and commencement: -

- 1.1 These Regulations may be called the “Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2016”
- 1.2 They shall come into force with effect from the date of their final publication in official gazette.

2. Definitions: -

Unless the context otherwise requires, ---

- 2.1 “**Act**” means the Food Safety and Standards Act, 2006 (Act 34 of 2006)
- 2.2 “**Approval**” in the context of these regulations means permission to manufacture, distribute, sell or import any article of food and food ingredients, intended directly or indirectly for human consumption, that has not been permitted under any other regulation made under the FSS Act, 2006.
- 2.3 All other words and expressions used herein and not defined, but defined in the Act or rules and regulation made thereunder, shall have the meaning as assigned to the same in the Act, Rules or Regulations.

3. Scope: -

- 3.1 Only such article of food or food ingredients which have not been permitted to be manufactured, stored, sold, distributed or imported under any other Regulation under the Act shall require prior approval for being manufactured, stored, sold, distributed or imported under the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2016. Such articles of foods and food ingredients shall include:

- Novel foods or foods containing novel ingredients not having a history of human consumption in the country
- Food ingredients with a history of human consumption in the country but not specified in any other Regulation under the Act
- New additives and processing aids

- Foods manufactured or processed with the use of novel technology.
- 3.2 The provisions in these Regulations shall be read in conjunction with provisions of other Rules and Regulations made under the Act.

4. Procedure for grant of approval: -

- 4.1 The manufacturer or importer shall submit an application as per Annexure I & II along with requisite documents and fee to the Food Safety and Standards Authority of India (FSSAI).
- 4.2 FSSAI shall scrutinize the application along with the supporting documents and other information enclosed as per annexure I & II. The applicant may be asked to provide additional supporting documents, data or clarifications, if required.
- 4.3 Based on the safety assessment of the food product, the Chief Executive Officer of the FSSAI, or an Officer authorized by him, may either grant approval or reject the application.
- 4.4 Where approval is granted, the FBO shall submit certificate of analysis of the product on parameters relating to chemical, nutritional, microbiological, heavy metals, pesticide residues and naturally occurring toxicants to FSSAI.
- 4.5 The FBO may file an appeal before the Chairperson, FSSAI against any decision of rejection of his application.
- 4.6 The FBO may file review petition before the Central Government against the decision of the Chairperson, FSSAI and the decision thereon of the Government shall be final.
- 4.7 FSSAI may, for reasons to be recorded in writing revoke or suspend any approval granted to any FBO which shall be a binding on the FBO.
- 4.8 FSSAI may specify the amount of application fee and review this amount from time to time.
- 4.9 In the event of any health risk coming to the knowledge of the FBO in respect of the food for which approval has been given under this regulation, the FBO shall immediately suspend the import, manufacture, sale, or distribution of the said article of food and take steps to recall the same under intimation to FSSAI as per the procedure laid down in the Food Safety and Standards (Food Recall) Regulation, 2016.

- 4.10 All the Food Safety Officers or Designated Officers shall immediately inform the Food Safety and Standards Authority of any complaint received regarding safety of food approved by the FSSAI under these Regulations.

Application formats for approval of non-specified food and food ingredient

Annexure I

Name of the applicant:

Mobile No. / Phone No. :

E-mail:

Organization Name:

Licence number if any:

Nature of Business:

Organisational Background:

Organization Address:

City:

State/UT:

Note: All communications will only be made through the above email and phone number.

ANNEXURE II

Applicants applying for Novel foods or foods containing novel Ingredients or processed with the use of Novel technology shall furnish the information as under

- I. Please specify the target group for the said proposed food, if any.
 1. Name of the proposed product/ Ingredient
 2. Justification of the name of the proposed product
 3. Provide the detailed composition of the product (with quantity of the ingredients and additives added in the product)
 4. Source of ingredient (animal, chemical, botanical or micro-biological)
In case of animal, botanical or micro-biological source genus and species may be mentioned
 - a. Any New Ingredient(s) [Please specify if the products had one or more new ingredients –meaning any ingredients which as on date is not listed in FSSR, or an ingredient which has been introduced for the first time in India.
 - b. Evidence proving that the product / ingredient is safe
5. Please provide the documentary evidence regarding regulatory status of the ingredients.
6. Indicate the RDA levels (as specified by ICMR) for vitamins, minerals and such other nutrients where RDAs are specified.
7. Functional use of ingredient/product
 - a. Specify the functional use of the proposed product in the target group for human consumption.
 - b. A brief description with documentary evidence of the same may be provided along with justification of data etc. for the quantity used.
8. Provide intended use of the new product
 - a. Specific benefit to the consumers or food manufacturers, if the proposed food product/ingredient is allowed.

- b. Specific advantages/disadvantages of the proposed food product to consumers and manufacturers along with justification, supported with documentary evidence.
 - c. Any other perceived use of the manufacture and resultant advantages and/or disadvantages may also be provided.
9. Certificate of analysis (COA) from third party NABL/ILAC recognized laboratories must be provided which demonstrates the compliance of the Ingredients/Products to the specifications as claimed by the applicant. Such COAs should include chemical parameters, nutrient levels, calorific value, metals contaminants (Pb,Cd,As, Cr, Cu, Sn, Hg, Ni), naturally occurring toxic substances, aflatoxins, pesticide residues, TPC,Y&M, E-Coli, Coli Form and freedom from Pathogenic organisms etc.
 - Validated test methods as needed for the analysis (with information on LOD, LOQ, sensitivity, repeatability, specificity etc.) shall be provided with references.
10. Proposed label in compliance with Section 23 of the FSS Act, 2006 and Food Safety and Standards (Packaging and Labeling) Regulations, 2011 to be attached with the following heading :-

‘PROPOSED LABEL FOR APPROVAL’
11. Method of Manufacture: Please provide the process used for manufacture of the product in detail.
12. Real time or accelerated Shelf Life/Stability of product (shelf life studies) shall be provided.
13. Specific conditions of storage must be provided along with detailed directions for use and expected ill effect due to failure to store the product under optimal conditions.
14. History of Consumption of product (Attach supporting documents)
 - a Geographical area of use (with established history of safe use in at least two countries, regulated by the Food regimes prevalent in EU, USA, Canada, Australia, Japan and China
 - b Average quantity of consumption
 - d Positive effects
 - e Negative/ Adverse effects

15. Safety Information: (Documents on risk assessment/toxicity studies to be attached)
- Response to this section may be based on safety or risk assessment review from published studies and safety studies conducted on the ingredient and food product by the applicant.
 - Safety information (literature based and if any additional study conducted)
 - Information on human studies, if any;
 - Toxicological studies
 - Results of Ames tests to test mutagenicity, chromosomal aberration tests, studies for reproductive toxicity, prenatal developmental toxicity studies may be provided.
 - Provide evidence to demonstrate that the proposed product or the ingredient will not adversely affect any specific population groups i.e. Pregnant women, lactating mothers, children, elderly or any other vulnerable group
 - History of new ingredient/product in other countries (Documents to be attached)
 - Allergenicity: Attach published or unpublished reports of allergenicity or other adverse effects in humans associated with the food consumption, Attach reports prepared by WHO or by other national or international agencies responsible for food safety or public health like Codex, USFDA, EU, FSANZ etc.
 - Information on dietary exposure, nutritional impact and potential impact on the consumer
16. Regulatory Status: Mention the countries where the product/ingredient is permitted for direct and/or indirect human consumption as food. If so, provide the level and purpose of consumption by the consumers with the relevant Regulations.
17. Copy of agreement of relationship of applicant and manufacturer and other entities involved in the food business of the proposed product (e.g. Marketer, importer, re-packer).

18. List of documents attached: The applicant shall attach an indexed list of documents in support of the application and identify these in relation to the information code herein.

21. All data documentary evidence provided by the applicant must be from international peer reviewed journals, international bodies including WHO and FAO. Only complete records/studies shall be provided.

Name and Signature of the Applicant.

Application for Food ingredients with a history of human consumption in the Country but not specified in any Regulation under the Act: -

- a. Product name
- b. Proprietary name
- c. Food Category System code
- d. Manufacture/Intend to Manufacture/Importer/Wish to Import/Marketer/ Wish to Market.
- e. Copy of license (if any).
- f. Detail Composition with quantity of ingredients and additives.
- g. Regulatory status of the additives.
- h. Source of the ingredients and additives (animal, chemical, botanical or micro- biological) In case of animal, botanical or micro-biological source genus and species may be mentioned
- i. End use declaration
- j. Complete Certificate of analysis
- k. Shelf life stability datasheet
- l. Label and Claims if any.
- m. Copy of agreement.
- n. Manufacturing process in brief
- o. Declaration whether RDA values of ingredients (like mineral/vitamins/amino acids /protein/metal etc) are as per ICMR guidelines along with the age group

Application format for New Additives.

- 1) Common name and Chemical name
- 2) Category/Class name of the additive (Please give the functional name of the additive Viz. Emulsifier/Preservatives/permitted sweeteners/anti-oxidants etc.)
- 3) Name, INS number and quantities of the food additives.
- 4) Purity (Food grade)
- 5) ADI/ status as per Codex
- 6) Level of use applied for
- 7) Source of the ingredient (animal, chemical, botanical or micro-biological)
- 8) Risk Assessment by appropriate agency.
- 9) Brief description of the functional role of the additive in the food (S) for which approval is required,
- 10) Regulatory status in FSS(FPS/FA) Regulation 2011
- 11) If response to the above is negative, Please give International approval status like CODEX, CFR (US), EFSA, FSANZ, etc.
- 12) Certificate of analysis as described in Annexure II
- 13) Shelf life stability data sheet
- 14) Label as per FSS (Packaging and Labelling) Regulations, 2011
- 15) Safety information
- 16) Method of Manufacture
- 17) Method of analysis
- 18) Copy of agreement
- 19) In case of flavouring agent specify whether it is Natural/ Nature Identical/ Artificial or Synthetic and in case of colouring agent provide (CI) Colour number where Applicable.
- 20) If the additive is used as a Processing Aid in the product, specify any residual levels that may be present in the final product.

Application format for Processing Aids & Enzymes.

- 1) Name
- 2) Synonym
- 3) Molecular weight, enzyme activity, purity, water content, ash content, microbial limit, storage standards may be specifically provided.
- 4) Specification
- 5) Source
- 6) Certificate of analysis as described in Annexure II
- 7) Shelf life stability data sheet
- 8) Label as per FSS (Packaging and Labelling) Regulations, 2011
- 9) Safety information
- 10) Manufacturing Process
- 11) Method of analysis
- 12) Copy of agreement
- 13) Risk assessment
- 14) International practices
- 15) Effect of Food enzyme/ processing aids in the final food.
- 16) End use (specify food in which it is to be used)
- 17) Residual limit in the final product.
- 18) ADI
- 19) Toxicity level
- 20) Adverse effect (If any)

Application format for Foods and food ingredients consisting of or isolated from microorganisms, fungi or algae:-

Data Required for Microorganisms used as Food (Directly Fed) or Used as a Source of Food				
S.No.				
1.	Nature of microbe	Bacterium	Yeast	Fungus
2	Name of the microbe	Genus	Species	Strain
3	Source	Indigenous	Imported	
		Isolated	Culture Collection	
4	If locally isolated	Deposited in the National Culture Collection (e.g.MTCC,NCDC)	Yes	No
5	If deposited in Culture Collection	Name & Address of Culture Collection	Reference No.	Receipt (Copy)
6	If bought from National Culture Collection	Name & Address of Culture Collection	Reference No.	Receipt (Copy)
7	If imported and privately Isolated	Country of origin		
		Name & Address of the Foreign Organization/Industry	Reference No.	Receipt (Copy)
8	If bought from International Culture Collection (e.g.ATCC,JCM)	Name & Address of International Culture Collection	Reference No.	Receipt (Copy)

9	Material Transfer Agreement between exporter/foreign entity and importer /manufacturer in India	Yes(Copy)	No	
10	If the organism has been genetically manipulated.	Yes	No	
11	Type of genetic manipulation	Induced mutation	Recombinant DNA Technology	
12	If Induced mutation	The nature of mutation	The name of the gene altered	
13	If Recombinant DNA Technology	The nature & Source of plasmid Vector		
		Foreign gene insert	Nature	Source
		Whether vector contains antibiotic resistance gene?	Yes/ No	The name of antibiotic & concentration
14		Any other marker on vector	Yes/No	Type
15	Any precautions /safety issues prescribed with the vector/ foreign gene			
16	Any Institutional Bio safety Mechanism in place			
17	Safety / GRAS Status of the microbe	Copy		

18	Declaration by the manufacturer/importer regarding safety and end use	The undersigned verifies that all ingredients are approved for use by the Export Country National Regulator and/or appear on their GRA Slist (Name of the Regulatory Agency), and each product is intended for human consumption and is available for sale in the country of origin without restriction.
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- 1) Composition of the Product
- 2) Certificate of analysis as described in Annexure II
- 3) Shelf life stability data sheet
- 4) Label as per FSS (Packaging and Labelling) Regulations, 2011
- 5) Manufacturing Process
- 6) Method of analysis
- 7) Safety information
- 8) Copy of agreement