Voluntary _ Public

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FSSAI Publishes Procedures for New Product Approval

Report Categories:
Sanitary/Phytosanitary/Food Safety
FAIRS Subject Report
Exporter Guide
Product Brief

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Report Highlights:
This report highlights the "New Product Approval Procedure" published by The Food Safety and Standards Authority of India (FSSAI) on December 11, 2012. The new procedure supersedes all previous advisories and clarifications issued by FSSAI.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the following Government of India website http://www.fssai.gov.in/. The U.S. Government makes no claim of accuracy or authenticity.

On December 11, 2012, The Food Safety and Standards Authority of India (FSSAI) published "New Product Approval Procedure." The new procedure will supersede all advisories and clarifications regarding product approval issued previously by FSSAI.

The full text as published on FSSAI website is given below.

No. P 15025/24/2012-PA/FSSAI
Food Safety and Standards Authority of India
(Ministry of Health and Family Welfare)
FDA Bhawan, Kotla Road
New Delhi.

PROCEDURE REGARDING NEW PRODUCT APPROVAL PROCEDURE

Several advisories relating to procedures for obtaining Product Approval before application for license have been issued and published on FSSAI website. Authority has also received several queries and concerns from the Food Business Operators regarding the complexity and time lines for product approval. Further to streamline the product approval procedure and the licensing of these foods in a timely manner with due consideration to the safety of foods and public health as well as for the smooth continuance of trade the following procedure shall be followed:

a. All advisories and clarification regarding Product Approval issued previously will be superseded with the new procedure referred as "New Product Approval Procedure".
b. This shall come into force from the date of notification on the FSSAI website.
c. The following guidelines given below shall apply.

Foods or food categories under the Natural Products Association (NPA) procedure and required to obtain product approval:

a. Proprietary Foods that have been granted license under previous Acts/Orders (PFA, MMPO, MFPO etc) and have been in the market prior to 31st March 2011 or new food products intended to be placed on the market and **do not contain** Novel Foods, Functional Foods, Food Supplements, Irradiated Foods, Genetically Modified Foods, Foods for Special Dietary Uses or extracts or concentrates of botanicals, herbs, or of animal sources shall be granted product approval under the following condition:

    i. The FBO has provided a complete list of ingredients and food additives as mentioned on the label (copy of label to be attached for products in market) and
    ii. The FBO has provided the category number as applicable under the Indian Food Category Code.
    iii. Where the application is in accordance to conditions as in 1(a) above and in the format (Format

1a) – FSSAI shall grant Product Approval and the FBO may proceed to obtaining a license as provided under paragraph (2) below

a. Foods labeled as proprietary foods, whether licensed under previous Act/Orders or are intended to be placed on the market and contain Novel Foods, Functional Foods, Food Supplements, Irradiated Foods, Genetically Modified Foods, Foods for Special Dietary Uses or extracts or concentrates of botanicals, herbs or of animal sources shall apply for product approval and grant of provisional NOC as provided under paragraph (2) below
b. Foods products requiring product approval shall be made in the application form as provided by FSSAI (Format 1b). Further

    i. Safety documentation is required for all ingredients except for vitamin and minerals or food additives approved under FSSR 2011 or Codex (JECFA).
    ii. The FBO shall also declare the category under which he intends to market the product as specified under Section 22 – namely food supplement, food for special dietary uses, functional food etc or any other recognized under international regulations.

2. Licensing Conditions:

a. All licenses granted under the Product Approval Procedure shall be issued under Central Licensing Authority for a period of one year and thereafter they will be considered for migrated to the respective State Licensing Authority in accordance with the rules and regulations thereunder.
b. Products falling under Clause 1(a) of this advisory shall apply for license as per the general requirements as applicable to the food product under FSS (Licensing and Registration of Food Businesses) Regulations 2011.
c. Products falling under Clause 1(b) shall be considered for issuance of a Provisional No Objection Certificate (PNOC) only after grant of Product Approval and subject to the conditions as under:

    i. For new products which are yet to be placed on the market a No Objection Certificate (NOC) will beissued for application of license under conditions of the FSS (L&R) 2011 as applicable. Where the safety data is insufficient to make the determination the FBO will be called upon to submit the same prior to grant of an NOC.
    ii. In the case of products currently in the market both domestic and imports and licensed under previous Acts/Orders shall be granted a provisional NOC (PNOC) for a period not exceeding one year from date of granting of the NOC, on the condition that the FBO obtains the required Food/Ingredient/Additive approval in the stipulated time.
    iii. In case of rejection of application under the Approval Procedure the product under reference shall be recalled as per provisions laid down in FSSR 2011.

3. Fees:

a. For products under 1(a) a fee of Rs.25,000/- for a group of 5 products which are significantly similar will be collected. If the products are dissimilar Rs.25,000/- for each product will be collected.
b. For all products under 1(b) an application fee of Rs.25,000 is payable on each product application submitted except where the only difference in product composition are flavours or colours they may be grouped together and considered a single application for five products.
c. Where the applicant is informed that the application for food product/ingredient approval required

further safety assessment by the Scientific Panel an additional fee of Rs.25000 is payable.

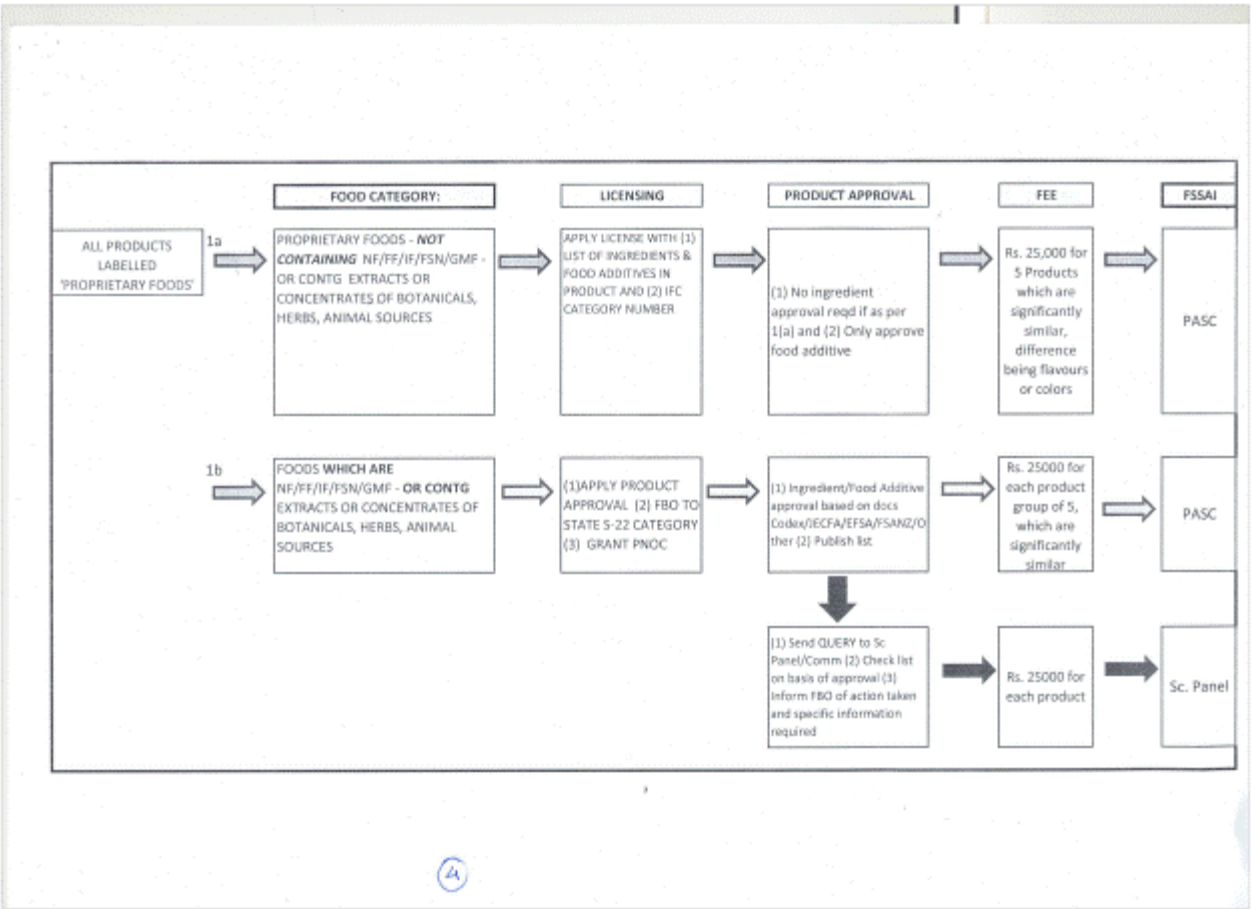
d. For all existing applications differential may be collected before going the product approval.

This issue with the approval of CEO, FSSAI

(Col. C.R. Dalal)
Director (In charge Product approval)

To

1. PS to CP
2. PPS to CEO
3. All Directors, FSSAI
4. All Central Dos/AOs
5. Website, FSSAI



APPLICATIONS FOR APPROVAL OF NEW PRODUCT/INGREDIENT:

FOOD SAFETY & STANDARDS AUTHORITY OF INDIA
PRODUCT APPROVAL PROCEDURE
Product falling under 1(a) of Advisory No

Date of Application
Registration No:

FOR FSSAI USE ONLY

A ADMINISTRATION DETAILS

1 Name of FBO

2 Contact Address (incl tel no etc)

3 Previous License Details

B PRODUCT DETAILS

Complete List of Ingredients	Complete List of Additives
1	1
2	2
3	3
4	4

C INDIAN FOOD CODE DETAILS

Name of Product as under above Code	
Code Number	
Product Label Attached	YES / NO

Note: (1) Use separate sheet for each product. (2) Use additional sheets if required)

APPLICATIONS FOR APPROVAL OF NEW PRODUCT/INGREDIENT

The following information is required for approval of new product/ingredient that has not been approved for use under the FSS Regulations:

1. **Administrative Information**

1.1. **Name of Applicant**:[Company Name] _____

1.2. **Complete Company Address:** [postal, telephone, fax, email]

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1.3. **Name of Contact Person** : _____ [Position, telephone fax, email]

[Authorization letter from the company shall be attached]

1.4. **Manufacturer Address**: manufacturer(s) of the substance (if different from above)

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1.5 Whether applicant is having the licence under FSS 2006. If yes give details.

2. **Technical Information**

2.1 Name of I.) New ingredient

II.) New product

2.1.1. Common Name: _____

2.1.2. Chemical or other name (in case of I above) _____

2.1.3. Name of food in which it is proposed to be used and concentration of usage (in case of ingredient)

2.1.4. Composition of product (in case of new product)

2.1.5. Brand Name (s) [if applicable] _____

2.2. **Functional use of ingredient/product**

2.3. **Technological Function**: [as applicable below in not more than 10 lines – supporting documents shall be attached]

2.3.1 Details on the functional / Technical need and advantage for the product/ingredient

2.3.2 Details of the benefits of a new product/ingredient

2.3.3 Details on the functional / Technical need for an increased level.

2.3.4 Provide information to demonstrate that the new product or the ingredient will not adversely affect any specific population groups (Pregnant women, lactating mothers, children, elderly etc.)

2.3.5 Specify the name of the food proposed to be marketed

2.3.6 Provide intended use of the new product, specific benefits the consumers or food manufacturers will get if the new food product/ingredient is allowed, specific advantages of the new food product to the consumers and manufacturers.

2.3.7 Specify the disadvantages attached if the manufacturer/consumer use the ingredient/product.

2.3.8 Provide information on the proposed usage of packaging material and its impact on the product / ingredient.

2.4. **Specifications/ Purity**

2.4.1. Composition of the product/ingredient

2.4.2. Percentage of each ingredient (nutrients and additives), name of additives with their category such as thickening agent, emulsifier, colour etc

2.4.3. Status of additives whether approved under FSSA Regulations, identify categories with INS no.

2.4.4. Food grade reference may be taken from Food Chemical Codex or any other internationally recognized source.

2.4.5. Tests for purity and conformance to Food Grade

2.5. **Method of Manufacture**: Brief description of the method, raw material source etc.

2.5.1 Detail of New technology involved if any.

2.5.2 Shelf Life Stability of product

2.5.3 Specific conditions of storage

2.6 **Safety Information**: Safety Approval of the product /ingredient by Recognized Safety Agencies. (Documents on risk assessment/toxicity studies to be attached)

2.6.1 History of new ingredient/product in other countries (Documents to be attached)

2.6.2 Attach published or unpublished reports of allergenicity or other adverse effects in humans associated with the food

2.6.3 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.

2.7 Regulatory Status: Mention the countries where the product/ingredient is permitted for use in the food. If so provide the level and purpose of consumption by the consumers and the relevant regulations be attached.

2.8 Method of Analysis:

2.8.1 Qualitative test of the subject material

2.8.2 Method of detection of the subject material when present in the mixture with foods and limit of this detection method.

Method of quantitative separation and analysis of the subject material when present in the food mixture. Limits of this method of analysis (LOQ, original reference, if published must be quoted)

2.8.3 How the subject material is to be specifically identified in presence of other food additives of similar nature?

2.9 List of documents attached:

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

2.9.2 Where the applicant requires certain documents to be treated as confidential the same shall be stamped on such documents and a formal request to this effect, shall accompany the application.

3. **Information on dietary exposure, nutritional impact and potential impact on the consumer**

3.1 Give details about the compositional analyses

3.2 Provide nutrient profile studies to demonstrate that the use of the new product or the new food ingredient will not cause a nutritional imbalance in the diet.

3.3 Provide information on the projected consumption levels of the new product(s) containing the new food ingredient, and frequency of consumption

3.4 Does the new product requires any specific labelling standards

3.4.1 If yes, Provide information on the proposed labelling

4. Efficacy – Health claim/Nutritional claim/Risk reduction claim

4.1 Published literature supporting the Health claim or Nutritional claim or Risk Reduction claim or clinical study carried out on the product to make such claims

4.2 Proposed label (as per labelling requirements under FSSA regulations, copy of prototype label to be attached).

5. Details of fees to be enclosed -

Name and Signature of the applicant

NB:

i) **Applicant will make such application with an initial payment of INR 25000 in the form of Demand Draft towards initial screening of the application by the "Approval Screening Committee". Subsequently, in case of "Category-B approval" the applicant will make an additional payment of INR 25000(non refundable).**

ii) Application fee in the form of demand draft shall be in favour of "Senior Account Officer, FSSAI" at New Delhi.