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FSSAI introduces product approval procedure in India

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

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Report Highlights:
This report summarizes the application process for introduction of new product/ingredient into India. The importers of such food products/ingredients can apply for license only after the product is approved by the Food Safety and Standards Authority of India.

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.

Announcement for approval of new food products/ingredients:

No. P.15025/219/11 – PA/FSSAI

Food Safety and Standards Authority of India

(Ministry of Health and Family Welfare)

The Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, provide a list of food businesses falling under provision of Central Licensing Authority. It interalia covers all food business operators manufacturing any article of food containing ingredients or substances or using technologies or processes or combination thereof whose safety has not been established through these regulations or which do not have a history of safe use or food containing ingredients which are being introduced for the first time into the country. They need to apply for Product Approval at FSSAI Headquarters before applying for Licence.

A copy of the application format is attached.

Source: FSSAI, Announcement regarding new product approval.pdf

APPLICATIONS FOR APPROVAL OF NEW PRODUCT/INGREDIENT: see the following page

Also see: Clarification relating Product Approval Procedure

Advisory regarding HS codes

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**

- Name of Applicant:[Company Name] _____
- Complete Company Address: [postal, telephone, fax, email]
- Name of Contact Person : _____ [Position, telephone fax, email]

[Authorization letter from the company shall be attached]

- Manufacturer Address: manufacturer(s) of the substance (if different from above)
- Whether applicant is having the licence under FSS 2006. If yes give details.

2. **Technical Information**

a. Name of I.) New ingredient
II.) New product

- Common Name: _____
- Chemical or other name (in case of I above) _____
- Name of food in which it is proposed to be used and concentration of usage (in case of ingredient)
- Composition of product (in case of new product)
- Brand Name (s) [if applicable] _____

b) **Functional use of ingredient/product**

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

- Details on the functional / Technical need and advantage for the product/ingredient
- Details of the benefits of a new product/ingredient
- Details on the functional / Technical need for an increased level.
- 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.)
- Specify the name of the food proposed to be marketed
- 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.
- Specify the disadvantages attached if the manufacturer/consumer use the ingredient/product.
- Provide information on the proposed usage of packaging material and its impact on the product /

ingredient.

d) **Specifications/ Purity**

- Composition of the product/ingredient
- Percentage of each ingredient (nutrients and additives), name of additives with their category such as thickening agent, emulsifier, colour etc
- Status of additives whether approved under FSSA Regulations, identify categories with INS no.
- Food grade reference may be taken from Food Chemical Codex or any other internationally recognized source.
- Tests for purity and conformance to Food Grade

e) **Method of Manufacture:**

- Brief description of the method, raw material source etc.
- Detail of New technology involved if any.
- Shelf Life Stability of product
- Specific conditions of storage

f) **Safety Information:**

- Safety Approval of the product /ingredient by Recognized Safety Agencies. (Documents on risk assessment/toxicity studies to be attached)
- History of new ingredient/product in other countries (Documents to be attached)
- Attach published or unpublished reports of allergenicity or other adverse effects in humans associated with the food
- 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.

g) **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.

i) **Method of Analysis:**

- Qualitative test of the subject material
- 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)

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

j) **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.

- 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**

a. Give details about the compositional analyses

b. b) 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.
c) Provide information on the projected consumption levels of the new product(s) containing the new food ingredient, and frequency of consumption
d) Does the new product requires any specific labelling standards

- If yes, Provide information on the proposed labelling

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

a) 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

b) 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 (non refundable) 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) The above fees is payable in the form of demand draft in favour of "Senior Accounts Officer, FSSAI" at New Delhi.

Source: FSSAI, **APPLICATIONS FOR APPROVAL OF NEW PRODUCT/INGREDIENT**

Please see below clarification regarding product approval procedure.

CLARIFICATION REGARDING PRODUCT APPROVAL PROCEDURE

It may be clarified that the applicants should apply for the approval of each product/ingredient separately for New Product/Ingredient Approval in the prescribed format and applications should be addressed to Director (PA), Food Safety and Standards Authority of India, FDA Bhavan, Kotla Road, New Delhi -110002. The envelope shall be super scribed with the heading New Product/Ingredient Approval.

It is also clarified that for obtaining product approval the Food business operator will make an application in the prescribed format with an initial payment of non refundable INR 25000 in the form of Demand Draft drawn in favour of Senior Account Officer, FSSAI towards initial screening of the application by the "Approval Screening Committee". The Approval Screening Committee will decide whether the product is falling under the Category A or Category B.

In case of Category A the Approval Screening Committee will deliberate and decide for the approval or rejection of the same on the basis of the information submitted by the applicant.
In case it requires further assessment in respect of safety etc. the application will come in Category-B and the matter will be assessed by the scientific panel/expert group and thereafter scientific committee for the approval or rejection of the same for which additional payment of INR 25000 (non refundable) to be remitted by the applicant.

Source: FSSAI, **CLARIFICATION REGARDING PRODUCT APPROVAL PROCEDURE**

Please see below advisory on HS Code

43F.No. 17-3/Enf/FSSAI/2011
Food Safety and Standards Authority of India

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 30.03.2012

Office Order (advisory on HS Code)

It may be clarified that H.S. Code is only code given for identification of the product/ chemical and it is not necessary that product/ chemical, if has H.S. Code, is approved product as per FSS Act, 2006. There is a separate procedure for getting approval of new product. It was decided and conveyed to NISG also the following procedure be adopted:

1. When H.S Code is available and is within the Chapters placed by FSSAI on website, the H.S Code is used.
2. When H.S Code is available but is available in Chapters other then placed on the website of FSSAI the Code will be transferred & placed under the category of miscellaneous Chapter.
3. H.S Code is not available at all. In such cases product name be mentioned.

Also, following disclaimer has been incorporated with HS Code in Online Food Licensing and Registration

System.

WARNING

"It is hereby clarified that H.S. Code is only code given for identification of the product/chemical and it is not necessary that product/chemical, if has HS Code, is approved product as per FSS Act, 2006. Please see the relevant provisions for confirming if product is already approved or a new product, in which case it will require product approval sanction under FSS Regulations."

We have also separately mentioned that application of new product should be sent to Director (PA) separately. In this way, it will be possible for IT Section to transport product code from other chapters and incorporate in the list of HS Codes against a newly created chapter called "Miscellaneous".

Sd/-
(Dr. D.S.Yadav)
Deputy Director (E-II)

To
1. All Directors, FSSAI
2. All Deputy Directors, FSSAI
3. All Central DOs, FSSAI
4. All Authorized Officer ,FSSAI
5. National Institute for Smart Government (NISG)

Copy to:
PPS to Chairperson for information please

Source: FSSAI**,** **ADVISORY ON HS CODE**