No. P 15025/01/2013-PA/FSSAI

Food Safety and Standards Authority of India

(Ministry of Health & Family Welfare)

Government of India

Date: 11th May 2013

Subject: Guidelines to be followed for product approval procedure.

Advisories relating to procedure for obtaining Product Approval (PA) from FSSAI have earlier been issued including their hosting on the FSSAI website. Feedback on the same has been received from various stakeholders regarding the complexity and time lines for product approval. Therefore, to streamline the product approval procedure with due consideration to the safety of food and public health, in supersession of earlier advisories, food products for which the standards are not specified under FSS Act 2006, Rules & Regulations made thereunder will be granted product approval. The following procedure shall come into force with immediate effect;

1 (a) Food products where the safety of its ingredients present are known and are permitted under FSS Regulation, 2011/Codex and other regulatory bodies like EU/FSANZ/USFDA etc. and the food product does not contain plants or botanicals or substances from animal origin will be granted product approval. The application in form 1 (a) along with the affidavit to be submitted by the Food Business Operator (FBO) for the product approval shall be accompanied by following documents:

i. Complete list of ingredients (specify the level of its use)

ii. Copy of the label for products in the market/to be placed in the market

iii. Category number of the product as applicable under the Indian Food Category Code

After scrutiny of the application and documents and on the condition that the documents submitted by the FBO are satisfactory, Product Approval Division (PAD) shall grant the product approval.

1(b) Food products where the safety of its ingredients present are known and are permitted under FSS Regulation, 2011/Codex and other regulatory bodies like EU/FSANZ/USFDA etc. and the food product contain ingredients including plants or botanicals or substances from animal origin shall be considered for Product approval/NOC. PA will be given to all products where safety assessment is

completed. NOC will be granted to food products in market where license has been granted under previous Act/Orders. The application in form 1 (b) along with the affidavit to be submitted by the Food Business Operator (FBO) for the product approval will be accompanied by following documents:

i. Complete list of ingredients (specify the level of its use)

ii. Copy of the label for products in the market/to be placed in the market

iii. Category number of the product under the Indian Food Category Code.

1(c) Food products falling under category 1 (b) above, *prima facie* where safety of the ingredients is insufficient to make a safety determination would be referred to respective Scientific Panels. Product approval shall be granted/ denied on the basis of risk assessment.

1(d) Products for which the safety of its ingredients and their conditions of use as stated therein and published by FSSAI or products whose ingredients are standardized or permitted under FSSR 2011 will not require further safety assessment except for authorization of the ingredients contained therein. The application in form 1 (d) along with the affidavit to be submitted by the Food Business Operator (FBO) for the product approval will be accompanied by following documents:

i. Complete list of ingredients (specify the level of its use)

ii. Copy of the label for products in the market/to be placed in the market

iii. Category number of the product under the Indian Food Category Code.

iv. Copy of PA/NOC issued by FSSAI

2. Safety data wherever required should be provided for all the ingredients.

3. The use of minerals/ vitamins/ proteins/ metals/amino acids/ their compounds should not exceed the Recommended Daily Allowance for Indians. In this regard, FBO shall follow the guidelines issued by Indian Council of Medical Research (ICMR) / National Institute of Nutrition (NIN) / World Health Organisation (WHO) / Food and Agriculture Organisation (FAO).

4. In case of rejection of application under the approval procedure, the product under reference shall be recalled as per the provisions laid down in FSS (Licensing and Registration of Food Businesses) Regulations 2011.

5. This procedure shall not be applicable if the food products or its ingredients are from the prohibited or banned source.

6. This procedure shall *ipso facto* be applicable to imported food products.

7. The terms used in the advisory will carry the meaning as defined in the FSS Act, 2006, Rules and Regulations made thereunder.

8. Application Fee: -

i. An application fee of Rs.25,000 (Non – Refundable) is payable in respect of each application. Since product approval is a safety assessment of ingredients, different permitted colours or flavours but having same composition shall be considered a single application.

ii. For cases wherein the application is forwarded to Scientific Panel additional fee of Rs.25,000 must be deposited for processing of the application.

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

9. Product approval application forms and the format of the affidavit are attached herewith.

Sd/-

(Pradip Chakraborty)

Director (Product Approval)

Copy to:

1. State Food Safety Commissioners
2. All Central DOs/ Aos

Affidavit

I, Mr./Ms./Mrs……S/o, D/o,W/o…….. of M/s……(name and address of the company),…… by occupation (designation) and R/o……..is importing /manufacturing…….. (name of ingredient/name of product) for last……(No. of years) under (Name of Act/order) food license No……. (Copy enclosed).

That in my official capacity mentioned herein above and I am competent/authorized to swear this affidavit.

1. I have applied for Product Approval vide my/our Application……. Dated……. I understand that the evaluation of the product will take time so in the interim I may be allowed to continue to market the product.
2. I further declare that the food business conducted or proposed to be conducted by/through me /shall conform to the Food Safety and Standards Act 2006 Rules & Regulations made thereunder.
3. I further declare that no court case against company is pending in any of the courts in the country for contravention of the provision of the FSS 2006, Act,/ rules & regulations made thereunder in respect of the product in question. Or (in the event of pending court cases, substitute this clause as under):
4. I/we further declare that there are pending cases against us for alleged contravention of provision of the Food Safety Standard Act, 2006/ rules/regulations made thereunder details of which are attached in the Annexure of the Affidavit. (Details/Disclosure of cases with case numbers and name of the court to be furnished in the annexure).
5. I further declare that I company shall maintain the record of the traceability to facilitate the recall operation of the food as per the requirement of the Food Safety and Standards Act, 2006 in case, the product is not approved by the FSSAI.

Date:

Place:

Signature and seal

FOOD SAFETY & STANDARD AUTHORITY OF INDIA
Product Approval Application form 1(a) / 1(d)

Date of Application

For FSSAI USE ONLY

A **DETAILS OF FOOD BUSINESS OPERATOR (FBO)**

1 (a)
Name of the applicant

1 (b)
Product Name

2 (a)
Contact Address
(Incl.tel.no. & E-Mail)

2 (b)
Manufacturing
Address

3
Previous License Details

B

PRODUCT DETAILS

List of Ingredients (in %)	List of Additives with INS No. (in %)
1	1
2	2
3	3
4	4

C

INDIAN FOOD CODE (IFC) DETAILS

Name of the product under IFC

IFC Number

DOCUMENTS TO BE ENCLOSED

1) **Product Label/Prototype Label**
2) **Certificate of Analysis of the product**
3) **Shelf Life of the product**
4) **End Use declaration of the product**
5) **Copy of NOC/PA issued by FSSAI in terms of 1(d)**

Name and Signature of the Applicant

Product Approval Application Form 1(b)

1. Details of Food Business Operator (FBO):

1.1. Name & Address of Applicant

1.2. Name of Contact Person: [Position, telephone, fax, email]

[Authorization letter from the company attached]

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

.....SAME ADDRESS.....

1.5 Whether applicant is having the license under FSS 2006. If yes give Details.

2.1 **Name of I.) New Ingredient**

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) **Food business operator will make such application with a payment of INR 25000 (non refundable).**

ii) Application fee in the form of demand draft shall be in favour of Senior Account Officer, FSSAI submitted for seeking product approval and is not refundable