

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) 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**