

Application format and summary sheet for approval of food additives under Food Safety and Standards Act, 2006

The Scientific Panel on Food Additives, flavouring, processing aids and materials in contact with food, constituted under section 13 of the Food Safety and Standards Act, 2006, in its 4th meeting held on 6th February, 2012 has approved the application format as well as summary sheet for approval of food additives.

Applicants should apply for the approval of food additives/enhancement of permitted food additives in other food products as well as increase the existing quantity of permitted food additives in the food product in the enclosed prescribed format. The application should be addressed to Director (PA), Food Safety and Standards Authority of India, 1st Floor, East Tower, NBCC Place, Bishma Pitamah Marg, Pragati Vihar, New Delhi-110003.

FOOD ADDITIVES-SUMMARY						
Section A		APPLICANT DETAILS				
APPLICATION No.		Name:	FOOD BUSINESS OPERATOR			
DATE		Supplier				
Submission		Food Manufacturer				
Request Information		Other				
Rejection						
Approved						
Other						
Section B		ADDITIVE DETAILS				
Common Name						
Chemical Name						
INS No.						
PURITY (Food Grade)				(Mention Food Grade Standard Reference)		
Section C		SAFETY AND ASSESSMENT				
Application is for:	Application Code ((Tick appropriate box)					
Previously Approved by FSSAI-Request for new food	Code	A-1				
Previously Approved by FSSAI-Request for increase level	Code	A-2				
Additive Not previously approved under FSSR	Code	NA				
Section D		ADI STATUS & LEVEL OF USE (Tick appropriate box)				
What is the ADI Status of the additive as per Codex	NOT SPECIFIED				Code	NSP
	ADI SPECIFIED (mg/kg)				Code	SP
Level of use applied for	GMP	mg/kg				
Risk Assessment by(tick appropriate agency(s))	JECFA	EFSA	FSANZ	USFDA		
	Other	Other	Other	Other		
Section E		CATEGORIZATION OF FOO (for which approval sought)				
Place food in the appropriate category	FSSR STD (if any)			Codex Food Category		
Section F		FUNCTIONAL USE (Technological function)				
Give a brief description of the functional role of the additive in the food(s) for which its approval is required (not more than 5-10 lines)						
REGULATORY APPROVALS- Food for which approval sought (only in case of New Additives)						
Tick Yes/No as applicable- (Optional to include other countries)	USFDA		EU		FSANZ	
	YES	NO	YES	NO	YES	NO
	YES	NO	YES	NO	YES	NO

APPLICATIONS FOR APPROVAL OF FOOD ADDITIVES

1. **Information to Applicants:** A submission is required for approval of a food additive for use in foods according to following conditions:
 - 1.1. New food additive that has not been approved for use under the Rules. [Code NA]
 - 1.2. Extension of in use of approved food additive not considered for use in food(s) under the hierarchical provisions of the Food Classification System [Code A-1]
 - 1.3. Use of an approved food additive in a food at a level higher than the maximum permitted /approved. [Code A -2].

All submissions shall be in the prescribed format given below – as required under the two different sub heads namely (1) Administrative Information and (2) Technical Information.

2. **Administrative Information:** In order to enable the office of the Food Authority to process applications expeditiously and contact the applicant as necessary for the purpose of evaluation of the application, the following information may be provided.

2.1. **Name of Applicant:**[Company Name] _____ [for use of additive in product]

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

.....

.....

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

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

.....

.....

2.5. **Type of application** [tick Code as applicable]

NA

A – 1

A - 2

2.6. **Date of Receipt:** _____ (of dossier)

2.7. **Application Number:** _____ (allotted by Office of Food Authority.)

2.8. **Date Accepted:** _____ [date from which the application is under process] [The Office of the Food Authority shall conduct a preliminary assessment of the documents received and request for any relevant information consistent with the type of application (Section 2.3)]

3. Technical Information

3.1. Name of Additive

- 3.1.1. Common Name: _____
- 3.1.2. Chemical Name [IUPAC/other]: _____
- 3.1.3. CAS Number [if defined]: _____
- 3.1.4. INS Number [if defined]: E number may be provided if not listed in rules
- 3.1.5. Brand Name (s) [if applicable] _____

3.2. Functional Class of Additive: [purpose for which required]

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

- 3.3.1. Details on the functional / Technical need for the additive
- 3.3.2. Details on the need for a new additive
- 3.3.3. Details on the functional / Technical need for an increased level.

3.4. Specifications/ Purity [only Code NA]:

- 3.4.1. Food grade reference may be taken from Food Chemical Codex or any other internationally recognized source.
- 3.4.2. Tests for purity and conformance to Food Grade

3.5. Method of Manufacture [only Code NA]: Brief description of the method, raw material source etc.

3.6. Safety Information [only Code NA]: Safety Approval by Recognized Safety Agencies such as JECFA, EFSA, and CFSAN etc.

3.7. Regulatory Status: Mention the countries where the additive is permitted for use in the food (s) applied for, such as Codex, US FDA, EU, FSANZ etc.

3.8. Method of Analysis:

- 3.8.1. For A-1 and A-2 type applications the method for sample preparation for product analysis may be given. The method of analysis may be cited giving

reference as available in Manual of Methods for Analysis under these rules or any other recognized Analytical Association.

3.8.2. For NA type applications the full method of sample preparation, development of method, standards etc may be provided. Actual analytical data may also be given for demonstrating capability.

3.9. List of documents attached:

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

3.9.2. 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.

3.9.3. A summary sheet (prescribed format) shall accompany the application (*separate sheet for each application*)
