

**QUESTIONNAIRE ON FOOD ADDITIVE**  
**(Other than Gras Additives)**

- 1. Designation of the subject material in respect of which the application is made.**
  - (a) Exact chemical designation to be given (including structural formula, if possible).
  - (b) Any international designation, abbreviated name, trade name and any commercially used scientific designation including all synonyms should be given.
  - (c) In case of mixture of substances, the name, synonym and chemicals, designation and structural formula of each component of the mixture are to be provided.
  
- 2. Specification and purity standard of subject material to be used are to be provided and major impurity which may be associated with it specifying their concentration.**
  
- 3. Chemical properties of the subject material.**
  - (i) Whether acidic, basic or neutral in reaction.
  - (ii) Solubility data in different solvents.
  - (iii) Reaction with common laboratory reagents.
  - (iv) Heat stability.
  - (v) Oxidisability and Redox-potential.
  - (vi) Common decomposition products.
  - (vii) Whether the subject material would undergo any change in presence of food material/material to which this additive is mixed when heated.
  - (viii) Whether the subject material would catalyse or retard any chemical or physical change in the food material with which it is mixed.
  
- 4. Physical properties of the subject materials,-**
  - (i) Physical state, including melting point and boiling point.
  - (ii) Colour.
  - (iii) Odour
  - (iv) Spectrophotometer properties.
  - (v) Any other special physical characteristic, having a bearing to its proposed use.

## **5. Method of analysis**

- (i) Qualitative test of the subject material.
- (ii) Method of detection of the subject material when present in the mixture with foods and limit of this detection method.
- (iii) Method of quantitative separation and analysis of the subject material when present in the food mixture. Limits of this method of analysis (original reference, if published must be quoted).
- (iv) How the subject material is to be specifically identified in presence of other food additives of similar nature.

## **6. Pharmacological properties**

- (i) Absorption sites and rates of absorption to be specified.
- (ii) Excretion chances of excretion and the rate of excretion.
- (iii) Its target organ and effect on the following systems to be specified.
  - (a) Central Nervous System.
  - (b) Cardiovascular
  - (c) Gastrointestinal.
  - (d) Renal.
  - (e) Hepatic.
  - (f) Haemopoitic
  - (g) Endocrinal.
- (iv) Effects on the composition of body fluids like acid Base Balance, Electrolytic composition etc.

## **7. Toxicological Investigation.**

- (i) Detailed evidence of toxicological tests must be provided which should include:-
  - (a) Types of test animal used.
  - (b) Dose level.
  - (c) Safety factor used for calculating dose level.
  - (d) Detail data of acute toxicity, sub-acute toxicity and chronic toxicity tests.
  - (e) LD 50 of the subject material with different animal (both oral and intera peritoneal)
- (ii) Whether the subject material was tested for carcinogenic, mutagenic and teratogenic properties? If so, what are the results of these tests?

- (iii) Whether the subject material was tested in experimental animals, fed on diet simulating “common poor Indian diet”. If so, with what result (give detail of experiment / experiments including composition of the experimental site).
- (iv) If the subject material was tested on gravid female animals for determination of its effect on the foetus, if so, with what result?

**8. What are the intended use of the subject materials?**

- (i) Types of food in which the subject material is to be used.
- (ii) At which concentration the subject material is to be used and the subsequent processes after addition.
- (iii) Residual level of the subject material in the food at the time of consumption.
- (iv) Specific purpose for which the subject material is intended to be used.
- (v) What specific benefits/ benefit the consumer will get, if the subject material is allowed to be used in foods?
- (vi) What specific disadvantages the consumers or food manufacturers are now experiencing in absence of the subject material?

**9. (a) Has the subject material already been proved in other countries? If so, relevant supporting documents may be appended indicating the food habits and food consumption/ capita of the people of that country.**

- (b) Has the subject material already been approved by International Organization like Codex /FAO/WHO Expert Committees? If so, relevant reference may be cited.

**10. (a) Is the subject material of specification quality standards already manufactured in the country from indigenous raw materials? If so, in what quality? Name of some principal manufacturers may be quoted.**

- (b) If not, whether the material will have to be imported or intended to be manufactured in the country.

**11. Name and address of the applicant / applicants.**

## QUESTIONNAIRE ON GRAS ADDITIVE

1. Name of Additive, Chemical designation, Scientific designation, abbreviated name and synonym, if any.
2. Food Products where it is proposed to be used.
3. Maximum Amount to be used.
4. Specification and purity standard of the Additive.
5. Method of Analysis (qualitative and quantitative) Product- wise.
6. (i) Functional use of Chemical.  
(ii) Technological Necessity in the product.
7. User Industry demand, if any (to be appended).
8. Codex Status
9. Name and Address of applicant – (with signature).