

Voluntary Report – Voluntary - Public Distribution

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Report Name: The FSSAI's 2021 Draft Amendments to the Approval of Non-Specified Food and Food Ingredients Regulation is now a Final Amendment in 2022

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report

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Report Highlights:

On October 11, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) published notification No. Std/EC/T(NSF-01) in the Gazette of India: Extraordinary (official gazette). The notification was subsequently published on the FSSAI website on October 14, 2022. The notification refers to amendments made in the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations (2017), pertaining to regulation (4) 'Procedure for grant of prior approval' of non-specified food and food ingredients. The draft amendments were published earlier on September 22, 2021, with comments having then been invited from the World Trade Organization (WTO) members.

DISCLAIMER: The information contained in this report was retrieved from the Food Safety and Standards Authority of India's (FSSAI) website <http://www.fssai.gov.in>. The Foreign Agricultural Service (FAS) Office of Agricultural Affairs at the U.S. Embassy in New Delhi, USDA, and/or the U.S. government make no claim of accuracy or authenticity. The Government of India has not officially endorsed this report. Import approval for any product is subject to local rules and regulations as interpreted by Indian officials at the time of product entry. [Note: Use Google Chrome to access the links that do not open in Internet Explorer. Indian host sites will geo-block site access on a rolling basis].

GENERAL INFORMATION

On October 11, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) published notification **No. Std/EC/T(NSF-01)** (see, Appendix I), in the Gazette of India: Extraordinary (official gazette). The notification was subsequently published on the FSSAI (food safety authority) website on October 14, 2022. This new FSSAI notification refers to amendments made in the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations (2017), relating to regulation (4) 'Procedure for grant of prior approval' of non-specified food and food ingredients.

FAS New Delhi (Post) in comparing the just published final amendment with the earlier draft amendment published on September 22, 2021, finds that the newly issued amendment now includes the FORM II. World Trade Organization (WTO) members had been previously invited to comment on the draft amendment. Through the inclusion of this new, additional form, the food safety authority may either grant approval or reject an application. All other information remains the same.

Post strongly advises interested stakeholders to thoroughly read the entire text of the FSSAI published final amendment. The full text of the final amendment is accessible on the FSSAI's website located at:

https://fssai.gov.in/upload/notifications/2022/10/6348fa8baa887Gazette_Notification_Product_14_10_2022.pdf

APPENDIX I: FOOD SAFETY AND STANDARDS (APPROVAL FOR NON-SPECIFIED FOOD AND FOOD INGREDIENTS) FIRST AMENDMENT REGULATIONS (2022)

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

NOTIFICATION

New Delhi, the 11th October, 2022

F. No. Std/EC/T(NSF-01).—Whereas the draft Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Amendment Regulations, 2021, were published as required by sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006) vide notification of the Food Safety and Standards Authority of India, F.No. Std/EC/T(NSF-01), dated the 22nd September, 2021, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 24th September, 2021;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (v) of sub-section (2) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), the Food Safety and Standards Authority of India hereby makes the following regulations to amend the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017, namely: -

1. (1) These regulations may be called the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) First Amendment Regulations, 2022.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 (hereinafter referred as said regulations), -

(1) for regulation 4, relating to the 'Procedure for grant of prior approval' the following shall be substituted, namely: -

"4. Procedure for grant of prior approval. - (1) The manufacturer or importer of non-specified food shall submit an application in **FORM – I** along with necessary documents and fee to the Food Authority.

(2) The Food Authority shall scrutinize the application and information provided by the applicant and on preliminary scrutiny, deficiencies, if any, shall inform the applicant within a period of forty-five days from the date of receipt of the application.

(3) The Food Authority may direct the applicant to submit additional supporting documents, data or clarifications, if required.

(4) The Food Business Operator shall submit the information sought for within a period of thirty days from the issuance of the letter.

Provided that the Food Authority may, for reasons to be recorded in writing, extend the timeline beyond thirty days.

(5) The Food Authority may appoint an expert committee or panel to examine the application submitted by the Food Business Operator.

(6) The Food Authority may either grant approval or reject the application, as per **FORM-II**, on the basis of the safety assessment of the article of food.

(7) After the approval of the product by the Food Authority, the Food Business Operator shall conduct and provide a post market surveillance data on relevant safety and efficacy parameters, within one year of placing the product in the market whenever asked by the Authority.

(8) *The Food Business Operator may file an appeal before the Chief Executive Officer of the Food Authority against any decision of rejection of application within a period of thirty days of the receipt of rejection letter and the Chief Executive Officer shall dispose off such appeal within a period of thirty days of its receipt and any delay beyond this shall be allowed with reasons to be recorded in writing.*

Provided that the Chief Executive Officer may allow the appeal after the period of thirty days if there are sufficient cause for the delay.

(9) *A Food Business Operator, who is aggrieved by the decision of the Chief Executive Officer of the Food Authority may file a review petition to be placed for consideration of the Chairperson of the Food Authority, within a period of thirty days from the date of issue of appellate order and such review shall be disposed off within a period of thirty days of its receipt and any delay beyond this shall be allowed with reasons to be recorded in writing.*

Provided that the Chairperson may allow the appeal after the period of thirty days if there are sufficient cause for the delay.

(10) The Food Authority may, for reasons to be recorded in writing, suspend or revoke any approval granted to any food business operator.

(11) The Food Authority may review from time to time, the amount of fee for filing an application and the fees paid by the applicant for processing of application shall not be refunded under any circumstances.

(12) The Food Business Operator shall, after grant of approval apply for license as per the procedure specified in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

(13) The Food Safety Officer and Designated Officer shall immediately inform the Food Authority of any complaint received regarding safety of any product approved by the Food Authority under these regulations.

(14) If a Food Business Operator has reason to believe that the food for which the approval has been granted poses any risk to health, he shall immediately suspend the manufacture, import, sale, or distribution of such article of food and take steps to recall the same under intimation to Food Authority in accordance with the provisions of the Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

FORM – I

(See sub-regulation (1) of regulation 4)

(Application for approval of non-specified food and food ingredient)

1. Application for*(Please tick (√) only one): -

- Novel food#
 - Novel food product
 - Novel food ingredient
 - Processed using novel technology
- Additive
 - Not listed in Food Safety and Standards Regulations (FSSR)
- New processing aid/enzyme
 - Not listed in FSSR
- Non-specified food, please specify,
 - New botanical
 - New fruit or fruit based product
 - Probiotic and Prebiotic
 - Any other, please specify

*Data in Form I. 3(d) shall be submitted, in case the application pertains to any of the categories listed above and consists of or is isolated from microorganisms.

#For the purposes of these regulations novel food is a food that may not have a history of human consumption; or may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption; or a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.

2. General information. – (1) Name of the applicant

(2) Name of the authorised person

(3) Mobile No. / Phone No.

(4) E-mail (All communications will only be made through the above email and phone number)

(5) Name of the organisation

(6) Address of the organisation/registered office

(7) Licence number, if any

(8) Name and address and contact details of the premises where the product covered in the application is manufactured or processed.

(Note: If this is different from the response to query 5 and 6 provide details including regulatory licenses applicable to the premises and provide name and contact details of the representative)

(9) Nature of business

(10) Name of the product for which application is submitted

(11) Justification of the name

(12) Proposed product category

(13) Source of food ingredient(s) (animal, chemical, botanical or micro-biological)

(14) In case of animal, botanical or micro-biological source, genus and species of the organism shall be mentioned

(15) Functional benefits

15.1 health benefits claimed for the product and on the label, if applicable

15.2 'end use declaration' for product/pre-mix /ingredient /additive imported or manufactured for supply to other *Food Business Operators*

Note: applications covered under 15.2 above shall provide:

(a) Data comprising proposed formulation(s), usage levels, directions and duration for use of the formulation, specification of the formulation(s) and shelf life study results (accelerated stability study results are acceptable).

(b) An undertaking by the authorized signatory stating that all the conditions communicated by the Authority in the approval letter shall be informed in writing to each of the FBOs to whom the material would be supplied for strict compliance. Any modification in the above conditions would necessitate prior approval of the Authority.

(16) Certificate of analysis from a third party laboratory, accredited by National Accreditation Board for Testing and Calibration Laboratories /International Laboratory Accreditation Cooperation, shall be provided. The certificate of analysis shall include physical, chemical and microbiological parameters relevant to the product along with validated test methods and other test methods, if any with references wherever applicable.

(17) Manufacturing process in brief (flow sheet with details).

(18) Regulatory status (Mention the countries where the product is permitted for direct or indirect human consumption as food. If so, provide the level and purpose of consumption by the consumers with the relevant regulations along with the documentary evidence).

(19) Copy of agreement of relationship of applicant and manufacturer and other entities involved in the food business of the proposed product, namely, marketer, importer, re-packer.

(20) Safety Information (Documents on risk assessment or toxicity studies)

(a) The information shall be based on safety or risk assessment review from published studies (Indexed journals) and safety studies conducted on the ingredient or food product by the applicant adopting Organization for Economic Co-operation and Development guidelines or safety studies as prescribed under Schedule 'Y' of D and C Rules, 1945 as amended (Safety data to be summarized in **Annexure A**).

(b) Provide evidence to demonstrate that the proposed product or the ingredient will not adversely affect any specific population groups that is pregnant women, lactating mothers, children, elderly or any other vulnerable group.

(21) Claim support documentation (Provide evidence to support the intended health benefit claims through robust scientific studies including human intervention studies or human clinical studies. Provide supporting published literature (Indexed journals), results of in-vitro and in-vivo studies and studies done on population relevant to India (Health benefit data to be summarized in **Annexure B**) if applicable, as provided in Food Safety and Standards (Advertising and Claims) Regulations, 2018.

(22) Copy of the proposed product prototype label as per relevant Food Safety and Standards Regulations.

(23) Declaration to conduct and provide post marketing surveillance data in specific cases if indicated in the Form II.

(24) Declaration to keep the information shared by the firm in Form I as confidential.

3. Additional specific information. - (1) Novel food or novel food Ingredients or food processed with the use of novel technology: -

(a) The target group for the said proposed food, if any

(b) Detailed composition of the product (with quantity of the ingredients and additives added in the product)

Any new ingredient (Please specify if the product has one or more new ingredients which as on date is not listed in Food Safety and Standards Regulation, or an ingredient which has been introduced for the first time in India)

(c) Details of new technology

(d) Safety Information (Documents on risk assessment or toxicity studies to be attached)

(i) Information on human studies including dietary exposure, nutritional impact and potential impact on the consumer, if any

(ii) Toxicological studies including results of Ames tests to test mutagenicity, chromosomal aberration tests, studies for reproductive toxicity, prenatal developmental toxicity studies

(iii) Allergenicity (published or unpublished reports of allergenicity or other adverse effects in humans associated with the food consumption; may include reports prepared by World Health Organization or by other national or international agencies responsible for food safety or public health)

(e) History of consumption of food product/food ingredient (attach supporting documents)

(i) Geographical area of use (with established history of safe use in at least two countries, with well-established regulatory status)

(ii) Quantity of consumption

(iii) Duration of consumption (in years)

(2) New additives: -

(a) Chemical name and International Numbering System No.

(b) Purity (food grade or equivalent)

(c) Acceptable Daily Intake specified by Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives or any other risk assessment body

(d) Proposed level of use in food category

(e) In case of colouring agent provide (Colour Index) colour number, where applicable

(3) New processing aids including enzymes: -

(a) Specification

(b) Enzyme activity

(c) Purity including total organic acid (as per the standards)

(d) Residual limit in the final product (in case of processing aid)

(4) Articles of food and food ingredients consisting of or isolated from microorganisms, bacteria, yeast, fungi or algae: -

S. No.	Data required for microorganisms used as Food (Directly Fed) or used as a source of food ingredients			
1.	Nature of microbe	Bacterium/Yeast/Fungus/Algae		
2.	Name of microbe	Genus	Species	Strain
3.	Source	Indigenous	Imported	
4.	If locally isolated	Isolated		
		Deposited in the national culture collection centre (eg- Microbial Type Culture Collection and Gene Bank, National Collection of Dairy Cultures, Indian Type Culture Collection)	Yes	No
5.	If deposited in a national culture Collection centre	Name and address of Culture collection centre	Reference No.	Receipt (Copy)
6.	If bought from national culture collection centre	Name and address of Culture collection centre	Reference No.	Receipt (Copy)
7.	If imported and privately Isolated	Country of origin		
		Name and address of The Foreign organization/Industry	Reference No.	Receipt Copy
8.	If bought from an international culture collection centre (e.g. American Type Culture Collection centre, European Culture Collections Organisation)	Name and address of International Culture Collection Centre	Reference No.	Receipt (Copy)
9.	Material Transfer Agreement between exporter/ foreign entity and importer/ manufacturer in India	Yes (Copy)	No	
10.	If the organism has been genetically manipulated.	Yes	No	
11.	Any institutional bio safety mechanism in place			
12.	Safety/Generally Recognized as Safe status of the microbe: Export Country National Regulator or appear on their Generally Recognized as Safe list (Name of the Regulatory Agency), or Qualified Presumption of Safety	Copy		
13.	Declaration by the manufacturer or importer regarding safety and end use	The undersigned verifies that all ingredients are approved for use by the Export Country National Regulator or appear on their Generally Recognized as Safe list (Name of the Regulatory Agency), or Qualified Presumption of Safety and each product is		

		intended for human consumption and is available for sale in the country of origin without restriction.
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Note: (1) Mention “not applicable” wherever necessary.

- (2) All data documentary evidence provided by the applicant shall be from international peer reviewed journals, international bodies including World Health Organization and Food and Agricultural Organization. Only complete records or studies shall be provided.

Annexure A

Format for providing summary of data for safety

1. in-vitro data

Test product (1.1)	System used Microbes / Cell lines / organ culture / other test system (specify) (1.2)	Concentration used (1.3)		Biomarkers performance indicators (1.4)	Observations (1.5)	Laboratory name / Reference publication (if any) (1.6)
		Negative control	Positive control			

2. Summary of in-vivo safety (pre-clinical toxicology) investigations

S. No	Test details	Material tested and their levels (2.1)			Animal species	Study parameters	Observations/ conclusions	Laboratory Name/ References or Citations (If published)
		Route	Exposure level/kg body weight*	Duration				
1.	Acute toxicity (2.2)							
2.	Long term toxicity (2.3)							
3.	Special Tests (specify)							

* Basis for calculating the intended exposure level/kg/day/number of days in the animal/species selected.

Note: Food Business Operator need not to submit details of in-vitro data if in-vivo data is provided to the Food Authority.

Annexure -I**1. Description to provide summary of in-vitro data**

- 1.1. Describe the material tested, purity, in case of botanicals or biological material provides information on their standardization / marker compounds tested / activity tested.
- 1.2. Provide information on bacteria, yeast or any other microbes against which testing was done including their National Type Culture Collection Centre / Account Number / details of cell lines / details of organ culture or tissue culture or any other system.
- 1.3. Provide information on Concentrations tested, negative and positive controls used in the experiments.
- 1.4. Provide information on what aspects were measured as outcome of the test. For example, IC50, cytotoxicity, dye uptake or reduction in dye uptake, preventing rate of growth.
- 1.5. Give brief summary of the results obtained, comparison with controls, and any dose response relations reported.
- 1.6. Provide complete reference of the publication. If the data is not published in peer reviewed journals, but forms a study report give details of the report covering where the study was undertaken, name of the institute or laboratory and its accreditation status and provide authenticated copy of the same. Provide full length paper copy of the most important study only and give a commitment to provide copy of other publications listed in the table when requested.

2. Safety studies: Provide justification on use of test material for normal human consumption.**2.1 Test compound profile and exposure level:**

- 2.1.1 Describe the material tested for purity, in case of botanicals/ biological material /food / food additives and colour additives along with their standardization / marker compounds tested.
- 2.1.2 Rationale for selecting the exposure level for experimental evaluation should be based on the intended /day / duration in human. The test exposure level should be calculated by standard body surface area method in laboratory animal selected.
- 2.1.3 Provide Rational for selecting the species.
- 2.1.4 Describe the rational for selected tests listed.

2.2 Acute toxicity: To determine toxic manifestations of the test substances preferably in two animals (mice, rats/rabbits) exposed to test compound within 24-hours period.

- 2.2.1 The study must provide the safety of a test compound at an exposure limit of 2 g/kg or at least 10 times of the intended human exposure level and route.
- 2.2.2 The data should provide the observations on body weight gain, Toxic signs and the severity, onset, progression and reversibility of the signs and mortality, if any, for 14 days after exposure of test compound.
- 2.2.3 In case of mortality the Necropsy findings along with histopathological report be enclosed.

2.3 Long term toxicity: To determine toxic manifestations of the test substance in two animals (mice and rats/rabbits) exposed to test material repeatedly as per the intended human use.

- 2.3.1 The study is required to be done with three exposure levels viz., Intended Human Exposure level (Therapeutic Dose (TD)), Average (2.5/5 X TD), High (5/10 X TD), In addition, vehicle control group should be included.
- 2.3.2 Dose level spacing should be designed to demonstrate a dose response and establish a no-observed-adverse-effect-level (NOAEL) or other intended outcome of the study.
- 2.3.3 The data should provide the observations on Physical, physiological, food intake, body weight gain, clinical-chemistry and haematology along with gross necropsy and histopathology of major and targeted organs. In case of mortality the animals may be subjected to gross necropsy and histopathology and a report may be enclosed.
- 2.3.4 In case the test material has a potential allergenicity/mutagenicity, the reports on special investigation have to be enclosed.

Annexure B

Format for providing summary of data for health benefit claims

1A. Summary of in-vitro data

Material tested (1)	Microbes/Cell lines /organ culture/ other test system (2)	Concentrations tested, negative and positive controls used (3)	Variables, biomarkers, performance indicators evaluated/measured (4)	Results obtained (5)	Reference of publication (6)

- Describe the material tested, purity, in case of botanicals or biological material provides information on their standardization / marker compounds tested / activity tested.
- Provide information on bacteria, yeast or any other microbes against which testing was done including their National Type Culture Collection Centre / account Number / details of cell lines / details of organ culture or tissue culture or any other system.
- Provide information on Concentrations tested, negative and positive controls used in the experiments.
- Provide information on what aspects were measured as outcome of the test. For example, IC50, cytotoxicity, dye uptake or reduction in dye uptake, preventing rate of growth.
- Give brief summary of the results obtained, comparison with controls, and any dose response relations reported.
- Provide complete reference of the publication. If the data is not published in peer reviewed journals, but forms a study report give details of the report covering where the study was undertaken, name of the institute or laboratory and its accreditation status and provide authenticated copy of the same. Provide full length paper copy of the most important study only and give a commitment to provide copy of other publications listed in the table when requested.

1B. Summary of in-vivo data

Material tested (1)	Laboratory animal used/knockout animals if used/ isolated organ if used / any other test system (2)	Concentrations tested, negative and positive controls used (3)	Variables, biomarkers, performance indicators evaluated/measured (4)	Results obtained (5)	Reference of publication (6)

- Describe the material tested, purity, in case of botanicals or biological materials provide information on their standardization/marker compounds tested/activity tested.
- Provide information on laboratory animal, knockout animals, live or anesthetized / isolated active organ of animals (isolated ileum, skin cultures, isolated heart as examples) or any other system.
- Provide information on Concentrations tested, negative and positive controls used in the experiments.
- Provide information on what aspects were measured as outcome of the test. For example, IC50, pharmacological activity measures, gene expression, specific protein uptake or regulation, biochemical markers, toxicology markers.
- Give brief summary of the results obtained, comparison with controls, and any dose response relations reported.

6. Provide complete reference of the publication. If the data is not published in peer reviewed journals, but forms a study report give details of the report covering where the study was undertaken, name of the institute or laboratory and its accreditation status and provide authenticated copy of the same. Provide full length paper copy of the most important study only and give a commitment to provide copy of other publications listed in the table when requested.

1C. Meta Analyses

S. No.	Participants (age, sex, condition, region and other relevant)	Interventions (Specify exact intervention used, number of participants)	Comparison (Specify exact comparison, number of participants)	Outcome evaluated	Pooled and quantified results and conclusions	Specific citation with copy as annexure

Summary of individual clinical studies section/table can be omitted if good intervention meta-analysis is available and summarized.

1D. Summary of human study data

Nature of study (1)	Material tested and their levels (2)	Nature of volunteers / subjects / population / patients (3)	Design of study and n =? (4)	Inclusion exclusion criteria (5)	Duration of study (6)	Variables measured (7)	Results obtained (8)	Reference of publication (9)

- Describe briefly the nature of study namely – open label, intervention study, randomization, blinding or population study or diet and outcome surveys or epidemiological data collection and analyses.
- Provide information on Concentrations tested, negative and positive controls used in the experiments.
- Give brief information on nature of subjects / volunteers / patients involved in the study. For example, normal healthy volunteers, pre-diabetics, mild to moderate hypertensive patients, volunteers with specified Body Mass Index etc.
- Give brief summary of the design of the study like matched panels, groups involved, cross over design, superiority study, addition study. State the number of volunteers or subjects or population or patients in each group giving details of number screened, number enrolled, number whose data is available, number drop outs. Also state the statistical analyses of the data reported and test of significance. Also provide approval status of the study by Department Review Board / Ethics Committee, adoption of informed consent.
- List the inclusion and exclusion criteria.
- State duration of the study – study period, duration of intervention, wash out period if any and period of observation post stoppage of intervention.
- Provide information on what aspects and variables were measured as outcome of the study. For example, pharmacological activity measures, biochemical markers, physiological parameters measured using instrumental technics like Electroencephalogram, *Treadmill Test*, echo, bone density, image analyzers etc. Provide information on adverse reactions and safety aspects evaluated including quality of life measurements and reported in the study. Specifically, state if the study does not report the safety or adverse reactions or no mention is made of this aspect. If any of the study provided in this summary table covers a Cochrane review or a meta analyses review provide summary of the same.
- Give brief summary of the results obtained, comparison with controls, and any dose response relations reported. Provide information on adverse reactions and safety aspects evaluated including quality of life measurements and reported in the study. Specifically, state if the study does not report the safety or adverse reactions or no mention is made of this aspect.

9. Provide complete reference of the publication. If the data is not published in peer reviewed journals, but forms a study report give details of the report covering where the study was undertaken, name of the institute or laboratory and its accreditation status and provide authenticated copy of the same. Provide full length paper copy of the most important study only and give a commitment to provide copy of other publications listed in the table when requested.
2. Summary of claim support data for claims pertaining to performance or technological advantages or consumer convenience and other claims which are not health benefit. The following type of claim statement provide examples of claims covered under 2.
- 2.1 Claims pertaining to bioavailability.
 - 2.2 Comparative content claims.
 - 2.3 Stability or reduction in degradation during cooking or processing.
 - 2.4 Claims related to adherence or sticking of cooking medium to the food processed.
 - 2.5 Retention of aroma or taste.
 - 2.6 Others, not covered above.

For the above claims appropriate scientific supporting data or documentation should be provided. In case of 2.1 details of the bioavailability study or bioequivalence study or comparative bioavailability study performed or reported in published scientific literatures or unpublished scientific study report. Provide detailed references and copies. In case of 2.2 results of analyses of relevant samples using validated analytical techniques conducted by an accredited laboratory would be required. Similar data would apply to claims belonging to 2.3 to 2.5. Focus would be on the scientific validity of the methods employed, expertise of the institution where study was conducted, and application of satisfactory statistical involvement.

3. For any of the claims under 1 or 2 above if any Intellectual Property Rights (IPR) exists provide the nature of the IPR with a commitment to provide copies of the same if demanded. For any of the claims under 1 or 2 above if claim support data includes regulatory approvals granted specifically or notified in regulations in other nations provide information in a summary table. In case of specific approvals granted state the same and authenticated copies of the same. For example, Generally Recognized As Safe listing or ingredients / product / claim approval received by the FBO or applicant.”

FORM-II

(See sub-regulation (6) of regulation 4)

(Approval/Rejection)

Application No:				
Date of application:				
Name of organisation:				
Name of the applicant:				
Registered office address:				
Authorised person:				
Name of the food product:				
Product category:				
Composition:				
Ingredients		Food Additives		
		Name	INS No	Limits (GMP or mg/Kg)
Application status:		Approved/Rejected.		

1. Conditions for approval:

2. Reasons for rejection, if any:

(Authorised Signatory)

S. GOPALAKRISHNAN, Chief Executive Officer

[ADVT.-III/4/Exty./328/2022-23]

Attachments:

No Attachments.