File No. SSDIV2-PA050(11)/2/2025-Standard-FSSAI

भारतीय खाद्य सुरक्षा एवं मानक प्राधिकरण

(स्वास्थ्य एवं परिवार कल्याण मंत्रालय)

(विज्ञान एवं मानक विभाग)

एफडीए भवन, कोटला रोड, नई दिल्ली -110002

Dated: 06th May, 2026

OFFICE ORDER

Subject: Implementing the process for prior approval and risk assessment through the single window system (ePAAS) – reg.

To ensure parity and transparency in risk assessment and approval mechanisms, it has been decided to implement a Single Window System through the electronic Product and Claim Approval Application System (ePAAS).

2) The ePAAS shall serve as a unified digital interface for the submission, processing, monitoring, and appeal/review of all applications related to the prior approval and risk assessment of products, ingredients, and claims, as applicable under relevant regulations.

3) In view of the above, the Authority has decided that all applications—accompanied by a complete dossier—for the risk assessment and approval of the following (with relevant regulations/clauses mentioned in Annexure I) shall be submitted exclusively through the ePAAS portal:

- Approval of Non-Specified Food and Food Ingredients (NSF&FI)
- Authorization of r-PET
- Approval of Claims
- Approval of Ayurveda Aahara
- FSMP
- Vegan Endorsement
- Notification of esters/derivatives/salts of vitamins, salts/chelates of minerals, and esters/derivatives/isomers/salts of amino acids
- Any other food, product, process, or system for which prior approval is required by the Food Authority under the provisions of the FSS Act, 2006, and regulations made thereunder, or as notified from time to time.

4) Unless otherwise specified in the relevant FSSR, the forms and formats for such applications shall be the same as those specified under the FSS (Approval of Non-Specified Food and Food Ingredients) Regulations, 2017.

5) Accordingly, effective June 1, 2026, all aforementioned applications seeking prior approval or authorization from the FSSAI shall be submitted only through the ePAAS portal (https://epaas.fssai.gov.in/login). Necessary guidelines, forms, and

formats will be available on the same portal. No manual, offline, or email-based applications shall be entertained thereafter.

This issues with the approval of the Competent Authority.

Digitally signed by Alka Rao
Date: 06-05-2026 13:31:13

(Dr. Alka Rao)
Advisor (Science & Standards & Regulations)
Food Safety & Standards Authority of India

To,

1. All Food Business Operators and other stakeholders

Copy to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. JS, FR, MoHFW
4. CITO, FSSAI, wih a request to upload on FSSAI website.

Annexure- I

Regulatory Requirements where Prior Approval in needed as per FSSR

Sl. No.	Regulation	Clause
1.	**Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011**	**2.2.6 (1)Vanaspati:** Vanaspati shall be prepared from any of the edible vegetable oils whose standards have been prescribed in these regulations or *from any other edible vegetable oil* with *prior approval* of the Food Safety and Standards Authority of India.
2.		**Regulation 2.10.6 (2) (III) (A)**: **Caffeinated Beverages** Any additional item or ingredient proposed to be added (other than the substances prescribed in the said table will be subject to *approval by* the Food Authority after safety assessment and substantiating scientific evidence.
3.		**Regulation 2.10.6 (3) (1): Non-carbonated Water Based Beverages (Non-Alcoholic)** Data of toxicological analysis to be provided for its *approval for the herbs other than those specified* in the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, and these regulations when added in the beverages.
4.		**Regulation 3 (27):** Cereal grains, legumes, fruits and vegetables mentioned in Indian Food Composition Tables published by National Institute of Nutrition, Indian council of Medical Research, and spices included in the list published by the Spices Board of India, may be used either as such or as processed ingredients including extracts, as a supplement or nutraceutical as applicable. However, for claiming specific health benefits prior *approval from the Food Authority* shall be obtained.
5.		**Regulation 3 (30):** Any single purified chemical entity listed in these regulations,

		except extracts of botanicals, which are to be sold as health supplement or nutraceutical or food for special dietary use or food for special medical purpose, as the case may be, is not permitted without *prior approval* of the Food Authority.
6.		**Regulation 3(33):** Food business operator shall seek approval of the *claims for the ingredients* or products covered under these regulations as per the Food Safety and Standards (Advertising and Claims) Regulations, 2018.
7.		**Regulation 4(6):** Any other claims in an article of food that are not drug claims may be allowed subject to prior approval of the Food Authority
8.		**Regulation 4(9)(iii):** If the health claims are product led, the food business operator shall notify to the Food Authority before putting the same in the market, by submitting relevant documents along with a copy of the label.
9.		**Regulation 6(2)(iv):** The food business operator shall apply to the Food Authority *for inclusion of any new nutrient or other substance* with a nutritional or physiological function, which has no history of use in India or that without evidence, establishing that the nutrient may result in certain nutritional and physiological benefits with justification for approval.
10.	**Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016**	**Regulation 7(iv):** A nutraceutical which is not provided in these regulations but its safety has been established in India or in any other country, shall be manufactured or sold in India only on prior approval of the Food Authority
11.		**Regulation 8(2)(iv) & 9(2)(v) :** Product with higher Recommended Dietary Allowances in food format (except tablet, capsule, syrup) may be allowed subject to prior approval of the Food Authority which shall be based on adequate scientific evidence.
12.		**Regulation 9(3)(c):** The statement “For the dietary management of _____” (with the blank to be filled in with the specific disease, disorderor medical condition for which the product is intended, and for which it has been shown to be effective) supported by appropriate scientific, and clinical or

		epidemiological data, and subject to its approval by the Food Authority
13.		**Regulation 12 (ii):** plant or botanical ingredient which is not specified in these regulations but its safety has been established in India or in any other country, may be manufactured or sold in India only after taking prior approval of the Food Authority.
14.		**Schedule I:** Vitamin D3 (cholecalciferol) from Lichen/Algae: The species of lichen/algae shall need prior approval of Food Authority)
15.		**Schedule I:** Suitable esters, derivatives and salts of vitamins and salts and chelates of minerals may be used. Food business operator shall notify in writing to Food Authority, whenever they use such esters, salts, chelates and derivatives. FBOs shall be required to submit additional safety data/information when requested by the Food Authority for such cases.
16.		**Schedule II:** Suitable esters, derivatives, isomers and salts of amino acids may be used. Food business operator shall notify in writing to Food Authority, whenever they use such esters, salts, isomers and derivatives. Food business operator shall be required to submit additional safety data or information when requested by the Food Authority for such cases.
17.		**Schedule VI:** The sources for ingredients listed under Schedule-VI shall only be from those listed/ specified under Food Safety and Standards Regulations. The chemically synthesized nutraceutical ingredients shall only be used with prior approval of the Food Authority.
18.	**Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017**	**Regulation 3:** Prior approval for manufacture, storage, sale, distribution, import, etc. No person shall manufacture or import any non-specified food or food ingredient, as the case may be, except with the *prior approval of the Food Authority.*
19.	**Food Safety and Standards (Advertising and Claims) Regulations, 2018**	**Regulation 11:** Approval of claims- The food business operator or marketer shall seek *prior approval from the Food Authority* for reduction of disease risk claims other than those that are defined.
20.	**Food Safety and**	**Regulation 7 (1) (e): Infant formula** may

	Standards (Foods for Infant Nutrition) Regulations, 2020.	contain L(+) lactic acid producing bacteria with *prior approval* of the Food Authority.
21.	Any other food/product/process/system for which prior approval is required by Food Authority under the provisions of the FSS Act, 2006 and regulations made thereunder or as notified from time to time	