

भारतीय खाद्य संरक्षा एवं मानक प्राधिकरण

(मंत्रालय कल्याण परिवार एवं स्वास्थ्य)

(विज्ञान एवं मानक विभाग)

एफडीए भवन, कोटला रोड, नई दिल्ली 110002

Dated, the 12 May, 2023

Notice

Sub: Applications received for approval of the products/ingredients formulated with vitamins and/or minerals above one RDA level-reg.

FSSAI has notified the Food Safety and Standards (Approval for Non-specified Food and Food Ingredients) Regulations, 2017 (*hereinafter referred as NSF regulations*) on 15.09.2017 for approval of non-specified food and food ingredients including novel foods. The applicants seeking approval of non-specified food and food ingredients have to submit an application in FORM – I of these regulations along with requisite fee and necessary documents substantiating safety and efficacy of product/ingredient formulations.

2. Drugs Technical Advisory Board (DTAB) in its 85th meeting held on 29.07.2020 at DGHS, Nirman Bhawan, New Delhi examined the Indian Council of Medical Research (ICMR) recommendations and recommended that vitamins with doses up to one RDA should be regulated under FSS Act. Other vitamin preparations having prophylactic and therapeutic claims should be regulated under the Drugs and Cosmetics Act, 1940 and Rules, 1945 including Schedule V of the Rules. Accordingly, Schedule V of the Drugs and Cosmetics Rules, 1945 should be amended by incorporating provisions clearly that vitamins with doses up to one RDA shall be regulated under FSS Act.

3. Expert Committee on non-specified food and food ingredients also recommended that products/ingredients formulated with vitamins and/or minerals above one RDA level are more akin to drug and such products/ingredients may not be considered for approval under the Food Safety and Standards (Approval for Non-specified Food and Food Ingredients) Regulations, 2017.

4. Further, the Authority examined the matter and decided that products/ingredients formulated with vitamins and/or minerals above one RDA level shall not be considered for approval under the Food Safety and Standards (Approval for Non-specified Food and Food Ingredients) Regulations, 2017.

This issues with the approval of Competent Authority.


(Dr. Harinder Singh Oberoi)
Advisor - S & S

To

1. Food Business Operators

Copy to:

1. PPS to CP, FSSAI
2. Sr. PS to CEO, FSSAI
3. All division Heads, FSSAI
4. CTO, FSSAI for uploading on FSSAI website