



File No. 18(4)2019/RCD/FSSAI-Nutra
Food Safety and Standards Authority of India
(A Statutory body under Ministry of Health and Family Welfare)
(Regulatory Compliance Division)

FDA Bhavan, Kotla Road,
New Delhi-110 002
Dated, the...^{11th} June, 2020

To

1. All Central Licensing Authorities
2. Commissioner of Food Safety of All States/UT's

Subject: Compliance with respect to Recommended Daily Allowance (RDA) values for license issued to products covered under FSS (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Foods for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016.

Section 22 of the FSS Act, 2006 permits use of nutrients in products such as health supplements, Nutraceuticals, etc. in amounts **not exceeding** Recommended Dietary Allowances (RDA) prescribed by Indian Council of Medical Research (ICMR).

Further, the **FSS (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Foods for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016** also specify that the quantity of nutrients added to food **shall NOT exceed** the Recommended Daily Allowance (RDA), as specified by ICMR, and in case, such standards are not specified, the standards laid down by international food standards body, namely, Codex shall apply.

2. FSSAI has also issued directions dated 07.01.2020 specifying RDA values of each of the vitamins, minerals and amino acids for ease of reference for regulatory staff and a guidance document is also placed on FLRS website for '*Filing of license applications for products under Nutraceuticals Regulations*', wherein it is stated that all Designated Officers shall refer to the direction dated 07.01.2020 issued by FSSAI regarding RDA values of nutrients.

3. Despite the above measures, it has come to the notice of FSSAI that licenses for the food products as per FSS (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Foods for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016 are being issued by the Licensing Authorities without duly

scrutinizing the RDA values of vitamins, minerals and amino acids in the products to be manufactured by the FBO applying for the license.

4. In view of above situation, a number of instances/references have been brought to the notice of FSSAI wherein the products which are exceeding the RDA values are being sold in the market under FSSAI License for which appropriately the manufacturer should have obtain license from the Central Drugs Standard Control Organisation (CDESCO) as per the provisions of Drugs & Cosmetics Act, 1940 and rules/regulations framed thereunder.

5. Accordingly, all the Central as well as State Licensing Authorities are hereby advised to strictly implement the limitation of '**Not More than one RDA**' for nutrients as per Section-22 of the FSS Act, 2006 and aforesaid Regulations while granting licenses to the FBOs except for Food for Special Medical purposes and Foods for Special dietary uses, where use of more than one RDA is permitted (as per Schedule-III of the Nutraceuticals Regulations).

In addition to above, they are also advised to undertake a review of RDAs mentioned by the FBOs in the existing licenses issued by their offices for health supplements, Nutraceuticals, etc. and issue notices to such manufacturers to direct them to undertake necessary modifications in compliance with the FSS Act, 2006 and the Regulations framed thereunder immediately.

The Licensing Authorities need to ensure that such products need to comply with RDA limitation. Stringent action may be taken against the defaulters.



(Shobhit Jain)

Executive Director (Compliance Strategy)

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1. CITO-for uploading on FSSAI's website
2. Advisor (Standards)- for information.