

Voluntary Report – Voluntary - Public Distribution

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Report Name: For the Sake of Clarity - India's FSSAI Issues Directive on Nutraceutical Regulations

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report

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Report Highlights:

On March 29, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued directive Std/SP-05/T(Nutraceutical-2022) [E-5184]. The directive states that the FSSAI has drafted a new framework and revised 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). The new framework is known as Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations (2022). This framework removes ambiguity by providing greater clarity to the regulation.

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 March 29, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued directive Std/SP-05/T(Nutraceutical-2022) [E-5184]. The directive indicates that the FSSAI has drafted the new framework and revised 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).

The new framework is known as Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations (2022) (FSS Nutra). This framework removes ambiguity by providing greater clarity to the regulation.

The forthcoming draft regulation and subsequent final regulation, along with their publication will take some time. In the interim, the FSSAI is operationalizing the provisions of the regulations listed in Annexure 1 from April 1, 2022, onwards. The new FSS Nutra Regulations (2022) supersede the 2016 published regulations and any amendments made thereunder.

The notification contains three annexes:

- Annexure 1: New Provisions Covered Under the Regulation
- Annexure 2: Schedules applicable to different categories of these regulations {Schedule I -IV}
- Annexure 3: List of Additives and Purity Criteria

The full text of the FSSAI directive is accessible on the FSSAI website located at:
https://fssai.gov.in/upload/advisories/2022/03/6243ef28079ceDirection_Nutra_30_03_2022.pdf

Attachments:

[220330-Direction_Nutra.pdf](#)