

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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Voluntary - Public

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India

Post: New Delhi

Additional Directives on Nutraceutical Foods Regulation

Report Categories:

Sanitary/Phytosanitary/Food Safety

Exporter Guide

FAIRS Subject Report

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Report Highlights:

On May 10, 2019, the Food Safety and Standards Authority of India (FSSAI) issued an additional directive to extend the timeline by three months on formulations containing vitamins and mineral combinations. This is the fifth directive issued on regulations relating to nutraceuticals, health supplements, food for special dietary use, food for special medical purposes, functional foods and novel foods.

General Information:

DISCLAIMER: The information contained in this report was retrieved from FSSAI's website: <http://www.fssai.gov.in/>. The Office of Agricultural Affairs, USDA and/or the U.S. Government make no claim of accuracy or authenticity.

Since the inception of the Nutraceutical Regulations in January 2018, FSSAI has published notifications on the use of specific ingredients in the manufacture of food products contained in the regulations. On May 10, 2019, FSSAI issued a directive to extend the timeline on the use of formulations containing vitamin and mineral combinations by three months, until June 30, 2019 or till further FSSAI orders, whichever is earlier. This is the fifth directive in the series that extends this timeline on formulations containing vitamins and mineral combinations, and the previous four directives were published on December 12, 2017, June 29, 2018, August 24, 2018, and December 31, 2018 respectively. The current notification also has a conditional clause stating that an ingredient, if not included in the list under Nutraceutical Regulations, will not be allowed to be used in any food product, unless if use of this ingredient is specifically allowed by other regulations under the Food Safety and Standards Regulations.

Background: On December 12, 2017, June 29, 2018, August 24, 2018, and December 31, 2018, FSSAI issued directives to inform food business operators about the compliance timelines for specific ingredients that are used in the manufacture of food products covered in their regulations, relating to nutraceuticals, health supplements, food for special dietary use, food for special medical purpose, functional foods and novel foods. Readers may refer to GAIN reports [IN8088](#), [IN8103](#), and [IN9001](#) for details on the previous directives.

The full text of the notification is pasted below is also available on FSSAI's website: <http://www.fssai.gov.in/>.

F. No. Stds/Nutra(DCGI)/FSSAI-2017 (Pt 1)
Food Safety and Standards Authority of India
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110 002


Dated, the 10th May, 2019

Subject: Implementation of Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (Nutraceutical Regulations).

In continuation to FSSAI's directions of even number dated 29.12.2017, 29.06.2018, 24.08.2018 and 31.12.2018 issued under Section 16 (5) of Food Safety and Standards Act, 2006 respectively on the above cited subject, the following decisions are further conveyed for information and necessary action:

- (a) The Food Business Operators (FBOs) are allowed to continue the food business of existing formulations containing 'Mere combinations of vitamins and minerals only up to one RDA in dosage formats such as tablets, capsules and syrups' for a period of three months till 30th June, 2019 or till further orders, whichever is earlier.
- (b) Further, an ingredient which is not allowed for inclusion under Nutraceutical Regulations vide aforesaid directions, is not allowed to be used in any food product, except if the use of this ingredient is specifically permitted by other regulations under Food Safety and Standards Regulations.

2. This issues with the approval of the Competent Authority, in exercise of the powers vested under Section 16 (5) of Food Safety and Standards Act, 2006.


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