

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Voluntary - Public

**Date:** 2/5/2019

**GAIN Report Number:** IN9001

## India

**Post:** New Delhi

### **FSSAI Directives for Nutraceutical Foods Regulation**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

Exporter Guide

FAIRS Subject Report

**Approved By:**

Tiffany Landry

**Prepared By:**

Radha Mani

**Report Highlights:**

On December 31, 2018, the Food Safety and Standards Authority of India (FSSAI) issued a notice that disallowed the use of several ingredients in nutraceutical foods. This is an addition to Appendix 1 of the previous FSSAI nutraceutical foods notification issued on June 29, 2018.

## 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.

On December 31, 2018, FSSAI published a third notification on the subject of Nutraceutical Foods Regulation and noted the following:

- (i) Allowing the use of the ingredient 'Vitamin D3' from lichen (*Cladonia rangiferina*) as a vegetable source in the products listed under Nutraceutical Regulations, until the time the proposed amendments on Nutraceutical Regulations are finalized and notified.
- (ii) Subject to compliance, mustard powder will continue to be used as an ingredient in products covered under the Nutraceutical Regulations.
- (iii) Discontinue certain ingredients (listed in the table below) effective immediately.
- (iv) Allow food business operators (FBOs) to sell existing formulations with simple combinations of vitamins and minerals, only up to one recommended dietary allowance, in dosage forms such as tablets, capsules, and syrups. This is effective for a period of three months from the date of the current notification, or until further orders are announced, whichever is earlier.

Background: On June 29, 2018, and August 24, 2018, FSSAI issued directives to inform FBOs about the compliance timelines for specific ingredients that are used in the manufacture of food products. These ingredients are 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](#) and [IN8103](#) to learn more details on the two previous directives.

Ingredients	Timeline and Remarks by the Panel
Raspberry Ketone Silica Angelica sinensis Chlorella growth factor Chaga extract Tea tree oil ( <i>Melaleuca alternifolia</i> )	FBOs to discontinue their use until the proposed amendment of the Nutraceutical Regulations are finalized and notified.
Oxalobacter Formigenes	FBOs to discontinue its use, with immediate effect, in products covered under the Nutraceutical Regulations, as it exhibits properties of a drug. No further manufacturing of products with this ingredient are allowed. If the products with listed ingredients are manufactured/imported under the Nutraceutical Regulations before June 29, 2018, their sales are allowed for only 30 days from the date of the current notification.

Paullinia cupana (Guarana) Saw Palmetto Notoginseng Pine bark extract from Pinus radiata Pine bark extract from Pinus pinaster	FBOs to discontinue their use with immediate effect as they lack adequate data, such as a history of safe usage in India for 15 years or a specific advantage of these plants over the already listed Indian plants/botanicals. No manufacturing of products using these ingredients is allowed. If products with these ingredients are manufactured and/or imported under the Nutraceutical Regulations before June 29, 2018, their sales are allowed for only 30 days from the date of the current notification.
---	--

The full text of the notification 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 31<sup>st</sup> December, 2018

**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 the direction issued under Section 16 (5) of Food Safety and Standards Act, 2006 dated 29.06.2018 and 24.08.2018 on the above cited subject, decision w.r.t the 14 ingredients listed under Appendix I of the direction dated 29.06.2018 are as follows:

- i) FBOs are allowed to continue to use the ingredient namely 'Vitamin D3' from lichen (*Cladonia rangiferina*) as veg source in the existing products covered under Nutraceutical Regulations, till such time the proposed amendment of the Nutraceutical regulations in this regard are finalized and notified.
- ii) FBOs are directed to discontinue the use of ingredient namely Raspberry ketone, Silica, *Angelica sinensis*, Chlorella growth factor, Chaga extract, Tea tree oil (*Melaleuca alternifolia*) in the products covered under Nutraceutical Regulations with immediate effect as no additional information has been provided by the applicant. No further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported under aforesaid regulations before 29.06.2018 are allowed to be sold only up to a period of 30 days from the date of this direction.
- iii) FBOs are directed to discontinue the use of ingredients namely '*Oxalobacter Formigenes*' in the products covered under Nutraceutical Regulations with immediate effect since they exhibit properties of a drug and no further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported under aforesaid regulations before 29.06.2018 are allowed to be sold only up to a period of 30 days from the date of this direction.
- iv) FBOs are directed to discontinue the use of ingredients namely *Paullinia cupana* (Guarana), Saw Palmetto, Notoginseng, Pine bark extract from *Pinus radiata*, Pine bark extract from *Pinus pinaster* in the products covered under Nutraceutical Regulations with immediate effect due to lack of adequate data such as history of safe usage in India for 15 years and also specific advantage of these plants over the already listed Indian plants/botanicals. No further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/

imported under aforesaid regulations before 29.06.2018 are allowed to be sold only up to a period of 30 days from the date of this direction.

- v) Based on the clarification provided by FBO that phytavail iron is mustard powder from *Brassica juncea* which is already covered under Schedule IV of the Nutraceutical regulations, it has been decided that no specific inclusion is required and ingredient mustard powder can be continued to be used in products covered under Nutraceutical Regulations subject to compliance with the aforesaid regulations.

2. Further, 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 from the date of this direction or till further orders, whichever is earlier.

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

Encl: As above

(Sunil Bakshi)

Advisor (Regulations / Codex)  
FSSAI, New Delhi.

To

1. All Commissioners of Food Safety of All States/UTs.
2. All Authorised Officers, FSSAI.
3. All Central Designated officers, FSSAI.

Copy for information:

1. PPS to Chairperson, FSSAI.
2. PS to CEO, FSSAI.
3. All Divisional Heads in FSSAI, New Delhi.