USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** December 05, 2022

Report Number: IN2022-0108

Report Name: India's FSSAI Rolls Out Re-Operationalized Nutraceutical Regulations

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report

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Report Highlights:

On November 28, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified on its website the Direction Std/SP-05/T(Nutraceutical-2022) (part-1)-Part (1) (October 18, 2022) (see, Appendix I). The FSSAI Direction indicates that the draft Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations (2022), as per provisions specified in its earlier directives of March 29, 2021, and May 5, 2022, is re-operationalized as of October 1, 2022. The FSSAI is issuing this directive assuming that the regulation in its final form is delayed for the foreseeable future.

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 REQUIREMENTS

On November 28, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified on its website the **Direction Std/SP-05/T(Nutraceutical-2022) (part-1)-Part (1) (October 18, 2022)** (see, Appendix I).

The FSSAI Direction states that the draft **Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations (2022)**, as per provisions specified in its earlier directives of March 29, 2021, and May 5, 2022, is re-operationalized as of October 1, 2022. The FSSAI is issuing this directive assuming that the regulation in its final form is delayed for the foreseeable future.

Background:

March 29, 2021: A new draft framework termed as **Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food** was notified with the aim of removing ambiguity and to provide greater clarity on the regulation (see, Appendix II).

May 10, 2022: In its previous directive issued on March 29, 2021, the FSSAI observed that a cross reference to Good Manufacturing Practices (GMP) table (Appendix 'A') of the regulation was provided for the list of food additives to be used at GMP levels. However, some of the additives, such as ammonium acetate, ammonium lactate, choline salt and esters, croscarmellose sodium, potassium hydrogen malate, sodium starch glycolate, and sucrose oligo esters – type I and II - which were present in Schedule VE of the previous nutraceutical regulations were not present in the GMP table (Appendix 'A') of the regulations. Also, the proteins and enzymes specified under Schedule III were inadvertently excluded for use in health supplements. To accommodate this discrepancy, the FSSAI allowed India's food business operators (FBOs) to use additives at the GMP level in addition to those additives listed under GMP table of the **Food Safety and Standards (Food Product Standards and Food Additives) Regulations (2011).** Enzymes and proteins listed under Schedule III of the **Nutraceutical Regulations (2022)** were allowed in the manufacture of health supplements (see, Appendix III).

The full text of the **Direction Std/SP-05/T(Nutraceutical-2022) (part-1)-Part (1) (October 18, 2022)** is located on the FSSAI website at:

https://fssai.gov.in/upload/advisories/2022/11/63849e4f8ba75Direction_Nutra_28_11_2022.pdf

The full text of the **Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food (March 29, 2021)** is located on the FSSAI website at:

https://fssai.gov.in/upload/advisories/2022/04/624ac1be799dbDirection_Nutra_30_03_2022.pdf

The full text of **the Food Safety and Standards (Food Product Standards and Food Additives) Regulations (2011)** is located on the FSSAI website at:

https://fssai.gov.in/upload/advisories/2022/05/627a160339d32Order_FSS_Nutra_10_05_2022.pdf

APPENDIX I: FSSAI DIRECTIVE DATED OCTOBER 18, 2022 (PUBLISHED ON THE FSSAI WEBSITE ON NOVEMBER 28, 2022)

File No. Std/SP-05/T(Nutraceutical-2022)(part-1)-Part(1)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi-110 002.

The 18 October , 2022

Subject: Direction under Section 18 (2) (d) read with Section 16 (5) of Food Safety and Standards Act, 2006 regarding operationalisation of FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022.

In exercise of the power conferred under section 92 of the Food Safety and Standards Act, 2006, FSSAI has framed draft FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 and the same were operationalised on 29.03.2022 superseding the *FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016*. The direction of 29.03.2022 was further revised *vide* direction dated 10.05.2022 to permit additional food additives; and enzyme / proteins for Health Supplements.

2. As the finalization of these draft regulations, 2022 is likely to take some more time before being notified, it has been decided to re-operationalize the provisions of these regulations as specified in the direction dated 29.03.2022 together with the provisions specified in the direction dated 10.05.2022, with effect from 1st October 2022.

3. This issues with the approval of the Competent Authority in exercise of the power vested under Section 18 (2) (d) and 16 (5) of Food Safety and Standards Act, 2006.

(Inoshi Sharma)
Executive Director (C S)

APPENDIX II: FSSAI DIRECTIVE STD/SP-05/T(NUTRACEUTICAL-2022) [E-5148] (MAY 10, 2022)

Std/SP-05/T(Nutraceutical-2022) [E-5148]
भारतीय खाद्य सुरक्षा और मानक प्राधिकरण
(खाद्य सुरक्षा और मानक अधिनियम, 2006 के तहत स्थापित एक वैधानिक प्राधिकरण)
एफडीए भवन, कोटला रोड, नई दिल्ली-110002

10th May, 2022

Order

Subject: Direction under section 16(5) of the Food Safety and Standards Act, 2006 regarding operationalization of FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022. [FSS (Nutra) Regulations, 2022]

This is in continuation to direction issued dated 29th March 2022 on the subject cited above.

2. In this regard, it is to mention that during examination of recently operationalized regulations following were observed:
   i. As per provision 5(4)(a) of Nutra regulations 2022, a cross reference to the GMP table (Appendix 'A') of the FSS (FPS&FA) Regulations, 2011 has been given for the list of food additives to be used at GMP levels. However, some of the additives namely- ***Ammonium acetate, Ammonium lactate, Choline salt and esters, Cross carmellose sodium, Potassium hydrogen malate, Sodium starch glycolate and Sucrose oligoesters-Type I and II*** which were present in the Schedule VE of the previous FSS (Nutraceutical) Regulations, 2016 are not present in the GMP table (Appendix 'A') of the FSS (FPS&FA) Regulations, 2011.
   ii. Further, as per provision 6(1)(b) of the FSS (Nutra) Regulations, 2022, the proteins and enzymes specified under Schedule III have been inadvertently excluded for use in Health supplement.
3. In view of the above, the following has been decided:
   i. FBOs may use additives as mentioned in para 2(i) above at GMP level, in addition to additives listed under GMP table (Appendix 'A') of the FSS (FPS&FA) Regulations, 2011.
   ii. Enzymes and proteins listed under Schedule III of the FSS (Nutra) Regulations, 2022 are allowed in the manufacture of Health supplement.
4. This issues with the approval of the Competent Authority.

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Bhaskar N
Advisor (Science and Standards)

APPENDIX III: FSSAI DIRECTIVE F.NO. STD/SP-05/T(NUTRACEUTICAL-2022) [E-5184]

F. No. Std/SP-05/T(Nutraceutical-2022) [E-5184]

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety & Standards Act, 2006)

FDA Bhawan, Kotla Road, New Delhi-110 002

29th **March, 2022**

Subject: Direction under section 16(5) of the Food Safety and Standards Act, 2006 regarding operationalization of FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022. [FSS (Nutra) Regulations, 2022]

In exercise of the power conferred under section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), the FSSAI has overhauled Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 and drafted a new framework to be called as FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 to remove ambiguity and bring more clarity.

2. The above mentioned draft regulations are in the process of draft publication and its final notifications are likely to take more time. Therefore, it has been decided to operationalize the provisions of these regulations as enclosed at ***Annexure 1*** with effect from 1st April 2022. Schedules as applicable to different categories of these regulations are enclosed at ***Annexure 2***. The list of additives and purity criteria is available at ***Annexure 3***.
3. FSS (Nutra) Regulations, 2022 shall supersede FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 and any amendments made thereunder.
4. This issues with the approval of the Competent Authority, in exercise of the power vested under the section 18(2)(d) read with 16(5) of the Food Safety and Standard Act,2006.

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Bhaskar N

Advisor (Science and Standards)

Attachments:

No Attachments.