

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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## India

**Post:** New Delhi

### **India Notifies WTO - Regs on Supplements – Functional - Novel Foods**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Exporter Guide

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**Report Highlights:**

On August 5, 2015, India notified to the World Trade Organization (WTO) a draft regulation related to food additives for nutritional supplements, functional and novel food products. The deadline to provide comments is October 4, 2015.

## General Information:

**DISCLAIMER:** The information contained in this report was retrieved from the Government of India (GOI) and WTO websites: <http://www.fssai.gov.in/> and [www.wto.org](http://www.wto.org). The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

The GOI's Food Safety and Standards Authority of India (FSSAI) published [new draft regulations](#) for nutritional supplements, nutraceuticals, foods for special diets, foods for special medical purpose, specialty foods that include ingredients based on *Ayurveda*, *Siddha*, *Unani* and other traditional Indian health systems, functional foods, and novel foods (See GAIN Report [IN5097](#)). Previously there were no specific regulations for nutraceuticals and dietary supplements.

On August 5, 2015, India notified a new draft regulation to WTO for comments (WTO Notification Number: G/SPS/N/IND/109). The deadline to provide comments is October 4, 2015.

Comments should be addressed to:

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## Summary:

- The new draft Regulation has defined the above mentioned categories of food on the essential composition, labeling, use of additives, contaminants and toxins, besides claims on health and nutritional values.
- The chapters as listed in the new Regulation are given below.

Chapter 1: Definitions

Chapter 2: Foods for Special Nutritional purposes or dietary uses (Generic)

Chapter 3: Food or health supplements

Chapter 4: Nutraceuticals

Chapter 5: FSDU-Other than infants, and those under medical advice

Chapter 6: FSMP

Chapter 7: Probiotic Ingredients

Chapter 8: Prebiotic Ingredients

Chapter 9: Specialty Foods containing ingredients based on Ayurveda, Unani and Siddha and Traditional Health Systems of India

Chapter 10: Novel Foods

- FSSAI has determined the general conditions for manufacture and sale of the above mentioned categories of foods and these are listed below.
1. No person shall manufacture, pack, sell, offer for sale, market or otherwise distribute or import any food products referred to in these regulations unless they comply with the requirements laid down under these regulations.
  2. The formulation of the foods shall be based on sound medical or nutritional principles and supported by validated scientific data, wherever required.
  3. No hormones or steroids or psychotropic ingredients shall be added in these foods.
  4. The labels shall clearly mention the purpose, the target consumer group and the physiological or disease conditions which they address, apart from the specific labeling requirements as mentioned against each type of food.
  5. The labels, accompanying leaflets/or other labeling and advertising of all types of foods, referred to in these regulations shall provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use and the format of information given shall be appropriate for the person for whom it is intended.
  6. A food which has not been particularly modified in any way but is suitable for use in a particular dietary regimen because of its natural composition, shall not be designated as “Food Supplements” or “Special Dietetic” or by any other equivalent term and such food may bear a statement on the label that “this food is by its nature “X” (“X” refers to the essential distinguishing characteristic as demonstrated by generally accepted scientific data) and such statement does not mislead the consumer.
  7. The Food Authority may suspend or restrict the trade of such foods as have been placed in the market that are not clearly distinguishable from foods for normal consumption nor are suitable for their claimed nutritional purpose, or may endanger the human health.
  8. The Food Authority may, at any time, ask a Food Business Operator (FBO) manufacturing and selling such special types of foods to furnish details regarding the history of use of the nutrients added or modified and their safety evaluation.
- The notification also includes schedules listing the nutrients and their usage levels for each of the above mentioned categories of food products. The details on the various schedules are:

Schedule I: List of Vitamins and Minerals for food or health supplements, special dietary and medical purpose foods

Schedule II: List of Vitamins and Minerals and their components

Schedule III: List of Amino Acids

Schedule IV: Values for Vitamins, Minerals and Trace elements allowed to be used in FSMP other than those intended for use by infants

Schedule V: ASU (Ayurveda, Siddha and Unani) Ingredients: Plant or Botanical Source

Schedule VI: ASU Ingredients: Animal Source

Schedule VII: ASU Ingredients: Mineral or Metal source

Schedule VIII (a): List of Food Additives for Food Supplements, Nutraceuticals and food containing probiotics and prebiotics

Schedule VIII (b): List of Food Additives for FSDU

Schedule VIII(c): List of Food Additives for SMPF (other than those intended for infant foods)

Schedule VIII (d): List of Food Additives for SMPF (other than those intended for infant foods);  
Formula for slimming purposes and weight reduction

Schedule VIII (e): List of food additives to be used for nutraceuticals; FSDU (other than infants);  
FSMP; foods containing probiotic ingredients and prebiotic ingredients; and food supplements

Schedule IX: List of sources of nutraceuticals

Schedule X: List of strains as probiotics (Live micro-organisms)

Schedule XI: List of Prebiotic Compounds