India notified its new standards for proprietary food to the World Trade Organization (WTO) and invited comments. The comment period for trading partners expires one month from the date it is notified on WTO website (www.wto.org).
Executive Summary:

On January 15, 2016, the Government of India (GOI) published Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016, in the official gazette relating to new standards for proprietary food. Though the new standards are operational with immediate effect, the GOI notified the amended standards to the WTO member countries and invited comments. The comment period for trading partners expires one month from the date it is notified on WTO website (www.wto.org).

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 and/or the U.S. Government make no claim of accuracy or authenticity.

The Food Safety and Standards Authority of India (FSSAI) amended the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011, related to standards for proprietary food and implemented them with immediate effect. With this amendment, nutraceuticals, health, and dietary supplements are no longer considered as proprietary foods and will be approved under a separate category. The new definition of proprietary food allows the manufacture, sale, distribution, and import of such foods without product approval. However, the onus of ensuring the safety of proprietary food has been shifted to the food business operator.

Regulation 2.12 relating to the definition of ‘Proprietary Food’ of the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 will now read as follows:

(1) Proprietary food means an article of food that has not been standardized under these regulations, but does not include any novel food, food for special dietary use, functional food, nutraceutical, health supplement and such other articles of food which the Central Government may notify in this behalf.

(2) Proprietary food shall contain only those ingredients other than additives which are either standardised in these Regulations or permitted for use in the preparation of other standardised food under these Regulations.

(3) Proprietary food shall use only such additives as specified for the Category to which the food belongs and such category shall be clearly mentioned on the label along with its name, nature and composition.

(4) Proprietary food product shall comply with the food additives provisions as prescribed in Appendix A and the microbiological specifications as prescribed in Appendix B of these Regulations and all other Regulations made under this Act.

(5) The Food Business Operator shall be fully responsible for the safety of the proprietary food.”

Comments, within 30 days from the date of notification in WTO website, should be sent to:

The Chief Executive Officer
Food Safety and Standards Authority of India
3rd Floor, Food and Drug Administration Bhawan, Kotla Road
New Delhi – 110002
Email: baranip@yahoo.com
Details of Notification: F.No.11/12/Reg/Prop/FSSAI-2016

- Publication in the Official Gazette: January 15, 2016
- Publication on the FSSAI website: January 25, 2016
- Date of Implementation: January 15, 2016
- Final date for comments: One month from the date notified on WTO website

Agency in Charge: Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, GOI.

The full text of the Gazette notification is attached below and is also available on FSSAI’s website: [http://www.fssai.gov.in/](http://www.fssai.gov.in/).

MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 12th January, 2016

F. No. 11/12/Reg/Prop/FSSAI-2016.—In exercise of the power conferred by clause (d) of sub-section (2) of Section 18 of the [Food Safety and Standards Act, 2006 (34 of 2006)](http://www.fssai.gov.in/), the Food safety and
Standards Authority of India, hereby makes the following amendment to the regulation 2.12 relating to ‘Proprietary Food’ of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely:—

Regulations

1. Short title and commencement. -(1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016.

(2) They shall come into force on the date of publication in the Official Gazette.

2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in regulations 2.12 relating to ‘Proprietary Food’, for the sub-regulations 2.12.1, the following shall be substituted, namely:—

“2.12.1: For the purpose of these regulations, -

(1) Proprietary food means an article of food that has not been standardized under these regulations, but does not include any novel food, food for special dietary use, functional food, nutraceutical, health supplement and such other articles of food which the Central Government may notify in this behalf.

(2) Proprietary food shall contain only those ingredients other than additives which are either standardised in these Regulations or permitted for use in the preparation of other standardised food under these Regulations.

(3) Proprietary food shall use only such additives as specified for the Category to which the food belongs and such category shall be clearly mentioned on the label along with its name, nature and composition.

(4) Proprietary food product shall comply with the food additives provisions as prescribed in Appendix A and the microbiological specifications as prescribed in Appendix B of these Regulations and all other Regulations made under this Act.

(5) The Food Business Operator shall be fully responsible for the safety of the proprietary food.”

PAWAN AGARWAL, Chief Executive Officer

[ADVT-III/4/Exty./329]

Note.—The principle regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011 and subsequently amended vide notification numbers:—

(i) F. No. 4/15015/30/2011, dated the 7th June, 2013;
(ii) F. No. P.15014/1/2011-PFA/FSSAI, dated the 27th June, 2013;
(iii) F. No. 5/15015/30/2012, dated the 12th July, 2013;
(iv) F. No. P.15025/262/13-PA/FSSAI dated the 5th December, 2014;
(v) F. No. 1-83/F/Sci.Pan-Noti/FSSAI-2012 dated the 17th February, 2015;
(vi) F. No. 4/15015/30/2011, dated the 4th August, 2015;
(vii) F. No P. 15025/263/13-PA/FSSAI, dated the 4th November, 2015;
(viii) F. No. P.15025/264/13-PA/FSSAI, dated the 4th November, 2015;
(ix) F. No. 7/15015/30/2012, dated the 13th November, 2015;
(x) F. No. P.15025/208/2013-PA/FSSAI, dated the 13th November, 2015 and