On August 22, 2016, the Government of India’s (GOI) Food Safety and Standards Authority of India (FSSAI) updated standards for proprietary food. These updated standards supersede the proprietary food standards that were made operational on January 13, 2016.
On August 22, 2016, the Food Safety and Standards Authority of India (FSSAI) updated the proprietary food standards with immediate effect. The updated standards are based on the comments received from various stakeholders. FSSAI also directed its States and Union Territory enforcement officials to implement the revised standards of proprietary food. Under the new revision, nutraceuticals, health, and dietary supplements would still be not considered as proprietary foods and will be approved under a separate category. The new revision adds the second paragraph in (1) and (2) below.

2.12.1: For the purpose of these regulations,-

(1) Proprietary food means an article of food that has not been standardised under these regulations, but does not include any novel foods, foods for special dietary uses, foods for special medical purposes, functional foods, nutraceuticals, health supplements and such other articles of food which the Central Government may notify in this behalf.

Provided that any deviation in quality parameters of a standardized food, as specified in the Food Safety and Standards Regulations made under the Food Safety and Standards Act, 2006 shall not qualify the resultant product as a proprietary food.

(2) Proprietary food shall contain only those ingredients other than additives which are either standardised or permitted for use in the preparation of other standardised food under these Regulations, except the ingredients which may be specified by the Authority from time to time.

Provided that a proprietary food may also contain vitamins and minerals in quantities not exceeding one RDA of the respective micronutrients.

Background:

On August 1, 2011, FSSAI published the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011. On January 15, 2016, FSSAI operationalized new standards for proprietary food by publishing Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016. Although these standards were effective immediately, FSSAI notified the amended standards to WTO member countries and invited comments. The new definition of proprietary food allowed the manufacture, sale, distribution, and import of such foods without product approval. However, the onus of ensuring the safety of proprietary food was shifted to the food business operator. For more details, please refer to GAIN Report IN6016 and IN6026.

The full text of the FSSAI’s new directive is pasted below and is also available on their website at: www.fssai.gov.in

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 sub-regulation 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 standardised under these regulations, but does not include any novel foods, foods for special dietary uses, foods for special medical purposes, functional foods, nutraceuticals, health supplements and such other articles of food which the Central Government may notify in this behalf.

Provided that any deviation in quality parameters of a standardized food, as specified in the Food Safety and Standards Regulations made under the Food Safety and Standards Act, 2006 shall not qualify the resultant product as a proprietary food.

(2) Proprietary food shall contain only those ingredients other than additives which are either standardised or permitted for use in the preparation of other standardised food under these Regulations, except the ingredients which may be specified by the Authority from time to time.

Provided that a proprietary food may also contain vitamins and minerals in quantities not exceeding one RDA of the respective micronutrients.

(3) Proprietary food shall use only such additives and at such levels, as specified for the Category or Sub-category under Appendix A of these Regulations, to which the food belongs. Such Category or Sub-category shall be clearly mentioned on the label along with the generic name, nature and composition of the proprietary food.

(4) Proprietary food shall comply with the microbiological requirements as specified in Appendix B of these Regulations. If no microbiological standards are specified for any foods or food categories in Appendix B of these regulations, proprietary foods falling under such food categories shall not contain any pathogenic microorganism at a level that may render the food product unsafe.

(5) Proprietary food shall also comply with the provisions, as applicable, of all other Regulations made under the Food Safety and Standards Act 2006. In addition, no health claims shall be made in respect of proprietary foods either on the product label or otherwise.

(6) The Food Business Operator shall be fully responsible for safety of the proprietary food in respect of human consumption.