

FAQs regarding Proprietary foods

FSSAI recognizes that a specific framework to manufacture and market proprietary food is required in accordance with the global best practices to provide certainty to all stakeholders while providing them with the flexibility to innovate.

An expanded list of food additives allowed to be used in different foods/food categories has already been operationalized through the “Notice for operationalization of standards of Food Additives for use in various Food Categories dated 23rd December 2015 issued by FSSAI”.

Earlier, Regulation 2.12 defined proprietary food as food that has not been standardized under these regulations. This regulation was amended and operationalized with effect from 15.01.2016 so as to provide framework for use of various ingredients in proprietary foods and puts the onus of food safety squarely on the Food Business Operators.

1. What is the date of implementation of this notice?

The provisions of this notification have been enforced with effect from 15.01.2016 and are required to be followed by the central and state food authorities and all food business operators.

2. What is the Scope of proprietary food?

- i) It covers non-standardized food for which no identity standards have been prescribed in the regulations. However, the categories of novel food, food for special dietary uses, functional foods, nutraceutical and health supplement are excluded from the scope of proprietary food as defined in the notification.
- ii) Any deviation in specific quality parameters (such as TSS, ash content etc.) of a standardized food shall not qualify the resultant product as proprietary food.

3. Will proprietary food complying with the provisions as laid in this notice require any pre- approval from FSSAI?

Proprietary foods complying with the provisions of this notification will not require any pre approval from FSSAI. The Food Business Operator (FBO) shall ensure that

products comply with these provisions and such FBO will be fully responsible for the safety of the proprietary food.

4. Which ingredients (other than additives) can be used in proprietary foods?

Any of the following can be used:

- i) Ingredients which are standardized or are permitted to be used in standardized products under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, can be used in proprietary foods.
- ii) Any ingredient other than those mentioned above, already approved under the erstwhile product approval process.
- iii) Further, proprietary foods containing added vitamins and minerals should not exceed 30 per cent. of Recommended Daily Allowance (RDA) for Indians.

5. Which additives can be used in proprietary foods?

The following Additives may be used in proprietary food:

- i) Food additives permitted in chapter 3 and Appendix A of Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011, for the particular food or food category (sub category) as amended from time to time.
- ii) Food additives permitted in specific food or food category (sub category) that are made operational as per the "Notice for operationalization of standards of Food Additives for use in various Food Categories dated 23rd December 2015 issued by FSSAI".

FBOs who have received approval for any additive other than those mentioned above, under the erstwhile product approval process may continue to use them.

6. Does licensing requirement change in anyway?

License for such proprietary foods shall be granted for the specific food or food category (sub category) as requested by the FBO in the application form in accordance with the licensing regulation without any requirement of product approval. FBOs can also get the new proprietary food incorporated in the existing license. Any existing proprietary products already included in the existing license shall remain valid.

7. What is the list of documents required for obtaining license for proprietary food?

Documents are required to be deposited with the State/Central Licensing Authority as per Annexure 2 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

8. How will an intermediate product to be used by another industry be governed under this regulation?

Intermediate products (food/food additive premixes) can contain ingredients permitted in this regulation and can contain additives as per Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, and/or Standards of food additives that have been made operational vide Notice dated 23rd December 2015 issued by FSSAI. It shall be the responsibility of the FBO to ensure that the finished product prepared using such premixes/intermediate products contain only those additive which are permitted under the regulations.

9. The regulation excludes ‘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’, from the definition of proprietary foods. How will these be regulated?

These special purpose foods will be governed by their respective regulations as and when notified. Such food products having product approval can continue to be manufactured/sold till such time that specific regulations in this regard are notified.

10. How will FBOs ensure compliance with the following provision in the notice - “such category shall be clearly mentioned on the label along with its name, nature and composition”?

i) “Category” – means category of the food as per the food category (sub category) system provided in the Food Safety and Standards (Food Product Standards and Food Additives) Regulation 2011, and permitted by the “Notice for operationalization of standards of Food Additives for use in various Food Categories dated 23rd December 2015 issued by FSSAI”.

For labelling purpose, the FBO can use product name along with the category number.

ii) Name, Nature and composition are as provided in the Food Safety and Standard (Packaging and Labeling) Regulation 2011, as below:

- a. "Name" – means the generic name of the product.
- b. "Nature" means description of the food contained in the package.
- c. "Composition" means list of ingredients in descending order.

11 What is the transition time for industry to comply with any labeling change that this notice may require?

The FBOs which have got approvals under the erstwhile product approval process can comply with the provisions of the new regulations within a period of six months from the date of notification.

12. What are the safety standards to be followed for proprietary food?

The proprietary food should comply with contaminants (chemical and microbiological) specifications prescribed for its ingredients, as applicable. In case of final product FBO should ensure that the food does not contain any pathogenic organism at a level that could render it unsafe.