



CONSULTATION PAPER ON CONDITIONAL LICENSING OF PROPRIETARY FOODS

14th July, 2021
Food Safety and Standards Authority of India,
FDA Bhawan, Kotla Road,
New Delhi.

Stakeholders are requested to furnish their written comments by 31st July, 2021 by email at enforcement1@fssai.gov.in.

For any clarification/information, contact:

Shri Vikas Talwar, Deputy Director (Regulatory Compliance), FSSAI, HQ, New Delhi

Email Id: vikastalwar.fci@gov.in

Contents

Chapter	Topic	Page No.
1.	Introduction & Overview of Regulatory Framework of Proprietary Foods	3-4
2.	Proposed changes	5
3.	Issues for Consultation	6
4.	Draft Order	7-8

CHAPTER-1

INTRODUCTION & OVERVIEW OF REGULATORY FRAMEWORK OF PROPRIETARY FOODS

Section 22 of the Food Safety and Standards Act, 2006 defines “Proprietary Food” as an article of food for which standards have not been specified but is not unsafe, provided that such food does not contain any of the foods and ingredients prohibited under this Act and regulations made thereunder.

2. Further, the Food Safety and Standards (Food Products Standards and Food Additives Regulations), 2011, under its sub-regulation 2.12 defines ‘Proprietary Foods’ as follows:

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

Provided that any deviation in quality parameters of a standardised 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 food products under the Food Safety Standards and Regulations and those food or ingredients mentioned in the Indian Food Composition Tables (IFCT), 2017, National Institute of Nutrition, except the ingredients which may be specified by the Authority from time to time and those specified under prohibition of hunting in the Indian Wildlife Protection Act, 1972 (53 of 1972):

Provided that a proprietary food may also contain vitamins and minerals in quantities not exceeding one Recommended Dietary Allowance 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. No health claims shall be made in respect of proprietary foods either on the product label or otherwise, unless it is substantiated by adequate and scientific evidence.

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

3. The definition of Proprietary Foods is intended to address those products for which vertical standards have not been set under FSSR, but are not unsafe, by ensuring safety of food products through effective use of already existing horizontal frameworks of nearest food categories as per FSSR. The safety of such foods has been relied upon by the Food Business Operators.
4. There are many instances where food manufacturers apply to obtain licenses for Proprietary Food products, which closely mimic standardized food products. Many products which have stringent vertical standards or have restrictions or prohibitions attached or specific packaging or labelling requirements tend to be closely duplicated under Proprietary Foods. There is no mandate for Proprietary foods to comply with vertical standards and they are tested only for horizontal standards of the nearest food category. The diversion towards Proprietary Foods is due to lack of explicit laws/guidelines on the subject and loose compliance requirements, due to which it has the risk of being put to wrong use by circumventing such stringent provisions under the standardized food products category by taking license under Proprietary Foods.
5. The implementation of sub-regulation 2.12 (Proprietary Foods) under FSS (Food Products Standards and Food Additives) Regulations, 2011 presents a lot of practical difficulties such as deviation from quality parameters of standardised products, use of a Proprietary Food as an intermediary in preparation of another Proprietary Food, applicability of standards of nearest food product/food category, placement of B2B products, etc. For instance, Honey with Ashwagandha can be allowed as a Proprietary Food, however, there is no requirement that the product should comply with the vertical standards of Honey as such. Similarly, other products containing mere addition of vitamins and minerals in a standardized food product are presently categorized as Proprietary Foods, which gives the manufacturers the option of deviating from the vertical standards/quality parameters of a standardised food vis-à-vis envisage a claim for added vitamins/minerals also.
6. At the same time, there is a need to facilitate use of standardized additives to food products without forcing manufacturers to apply for proprietary food licenses. The concerned Scientific Panels are already working on this proposal and are expected to come out with their recommendations soon.

CHAPTER-2

PROPOSED CHANGES

Presently, Proprietary food products are being licensed by Central Licensing Authorities only and being mapped to the nearest food category. In order to resolve the above mentioned issues, the following is proposed:

- a. **Conditional Licensing**- The provisions for 'Conditional licensing' in case of Proprietary Foods shall be enabled on FOSCOS, wherein CLAs shall report their remarks for each license application made for Proprietary Foods under a license application. The CLAs shall be required to provide their remarks w.r.t. nearest standardized food product for the Proprietary Food product applied for license, whether vertical standards of the nearest food product shall apply to the Proprietary Food product and if not, the justified reasons for which deviation is being allowed/rejected for grant of license and accordingly, impose justifiable conditions to be complied by the FBO w.r.t. the specific Proprietary Food product. The conditions so imposed while granting license shall be printed on the license against each product as a part of Product annexure and shall be visible to FBOs, consumers as well as SLAs/Regional Offices.

The concept of Conditional Licensing is intended to check the entry of such products into the market where composition of the product is diluted/diverted to avoid compliance with standardised food products and yet allow entry of value added food products which could not fit into the description of a standardised food product or are altogether different products made out of a mix of standardised food products.

- b. **Mapping of the Proprietary food products** Mapping of Proprietary Food Products to the nearest food products, wherever available and appropriate to ensure compliance with the vertical standards of standardized food products also. In case where the product cannot be mapped to any standardised food product, then it shall be mapped to nearest food category as is being presently done.

The above mentioned proposals would require amendments in the sub-regulation 2.12 of the FSS (Food Products Standards and Food Additives) Regulations, 2011. In addition, it would also require operational changes under the FoSCOS portal to incorporate provision of conditional licensing for CLAs for Proprietary Foods and mapping of Proprietary Food Products to both food products as well as food category, wherever applicable. However, while the conditional licensing can be enabled instantly, mapping of proprietary food products with nearest food product shall require time and shall be undertaken only after the necessary amendments in the Proprietary Foods regulations are done.

CHAPTER-3

ISSUES FOR CONSULTATION

In view of the discussion in the preceding chapters, the following questions are raised for seeking comments of the stakeholders. Responses to the questions are solicited with justification and supporting documents/examples, if any.

Question 1: Should FSSAI enable conditional licensing of Proprietary Foods by CLAs? What practical challenges can be envisaged in its operationalization?

Question 2: Should FSSAI enable mapping of Proprietary Food products with nearest food products? Are there any practical challenges?

Question 3: Is there any other proposal by way of which this diversion towards Proprietary Foods can be tackled?

CHAPTER-4

DRAFT ORDER

File No. Miscellaneous References-II/RCD/FSSAI-2020
Food Safety and Standards Authority of India
(A Statutory body under Ministry of Health and Family Welfare)
(Regulatory Compliance Division)

FDA Bhavan, Kotla Road,
New Delhi-110 003
Dated, the July, 2021

Draft Order

Subject: Conditional Licensing for Proprietary Foods-reg.

It has come to the notice of FSSAI that there are many instances where food manufacturers try to obtain licenses for Proprietary Food products, which closely mimic standardized food products. The diversion towards Proprietary Foods is due to lack of explicit laws/guidelines on the subject and loose compliance requirements.

2. In order to resolve these issues, it has been decided by the Food Authority to introduce 'Conditional Licensing' for license applications for Proprietary Foods. The concept of Conditional Licensing is intended to place a bar on entry of such products into the market where composition of the product is diluted/diverted to avoid compliance with standardised food products and yet allow entry of value added food products which could not fit into the description of a standardised food product or are altogether different products made out of a mix of standardised food products.

3. Under the FoSCOS portal, an option would be made available to all the Central Licensing Authorities to impose conditions on each of the Proprietary Food Product under a license application. The CLAs shall be required to provide their remarks w.r.t. nearest standardized food product for the Proprietary Food product applied for license, whether the vertical standards of the nearest food product shall apply to the Proprietary Food product and if not, the justified reasons for which deviation is being allowed/rejected for grant of license and accordingly, impose justifiable conditions to be complied by the FBO with respect to the specific Proprietary food product. The conditions so imposed while granting license shall be printed on the license and shall remain visible for FBOs, consumers as well as licensing authorities.

4. Certain general guidelines which are to be kept in mind while imposing such conditions/restrictions are as follows:

a. CLAs need not impose conditions on all Proprietary food products. Rather, CLAs should exercise prudence for imposing conditions generally in cases which seem to escape the rigor of standardized food products either by diluting or diverting the standards through some technological changes/minor addition/deletion, etc. The purpose of the condition should be clear and the condition should be practical, unambiguous and prone to test.

b. The conditions imposed by CLAs shall be suitably justifiable and should be backed by value judgment reflected by reasons recorded (under the Remarks section on FoSCOS).The conditions and remarks provided by CLAs shall be subjected to scrutiny by the Regional Offices and FSSAI HQs.

c. The conditions should not in any way overrule any of the FSSRs and in specific, the FSS (Prohibition and Restriction on Sales) Regulations, 2011.

5. The concerned Licensing Authorities are advised to keep strict vigil and sensitivities while exercising conditional licensing of food products.

Yours sincerely,

(Inoshi Sharma)
Executive Director,

To

All the Regional Directors, FSSAI
All Central Licensing Authorities, FSSAI