

File No. 15(15)2018/CLAs/RCD/FSSAI
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-110 002
Dated, the 06th November, 2020

To

All Central Licensing Authorities,
All Regional Directors

Subject: Exclusion of Food Category "13" (Foodstuffs intended for particular nutritional uses) from the scope of Proprietary Foods

Sir/Madam,

The Food Safety and Standards (Food Products Standards and Food Additives Regulations), 2011, under its sub-regulation 2.12 defines 'Proprietary Food' as *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.*

2. Further, the sub-regulation 2.4.1 (1) under FSS (Packaging and Labelling) Regulations, 2011 also states that an article of infant milk substitutes /infant foods, whose standards are not prescribed under Food Safety and Standards (Food Products standards and Food Additives) Regulations, 2011 shall be manufactured for sale, exhibited for sale or stored for sale only after obtaining the approval of such articles of food and its label from the Authority.

3. Since the FC 13 broadly covers Infant food products and products covered under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, in view of the above, it is inferred that the products covered under all the sub-categories under the Food Category 13, i.e. Foodstuffs intended for particular nutritional shall either have to comply with the standards set out in the respective regulations or have to seek product approval under FSS (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017. Hence, all such products cannot be licensed as Proprietary Foods in any case.

4. The existing database under FLRS was reviewed and it has come to notice that a few licenses under category 13 have been issued as Proprietary Foods. In order to prevent inadvertent errors and considering the sensitivity of the food category 13 and aligned law already in place, it has been decided to presently block food category 13 from the scope of Proprietary Foods under FoSCOS.

5. Henceforth, category 13 shall not be indicated under the Proprietary Foods in FoSCOS. Since this change on FoSCOS is likely to take a few days' time, the CLAs are requested to inform and advise all such food business operators who apply for FC 13 under Proprietary Category suitably. In case any such product is noticed, which merits FC 13 under Proprietary as per the law, same may also be informed to this office.

6. Further, all the CLA's are directed to identify such licenses granted earlier under Proprietary Foods with FC 13 and advise such FBOs to get them suitably modified under FoSCOS (without any modification fee up to 30th June, 2021).

7. It is hereby directed to ensure compliance of the above guidelines for all such prospective licenses with effect from the date of issue of this order. Difficulty, if any, in implementation of the above may be brought to the notice of the undersigned.



(Dr. Shobhit Jain)

Executive Director
Regulatory Compliance Division

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