15(31)2020/FoSCoS/RCD/FSSAIpt9

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety and Standards Act, 2006)

(Regulatory Compliance Division)

FDA Bhawan, Kotla Road, New Delhi - 110002

Food Safety Compliance System (FoSCoS) - https://foscos.fssai.gov.in

Dated, the 31 March, 2022

Subject: SOP for Mandatory Modification of old methodology License (initially granted from FLRS portal) or migration of State License for Manufacturing of Nutraceuticals and related products wef 01.04.2022 – reg.

FSSAI vide order number 15(31)2020/FoSCoS/RCD/FSSAI dated 28th May 2020 upon launch of FoSCoS portal, issued directions for the existing manufacturers to modify their license granted earlier through FLRS. The time period for mandatory modification [without fee] was allowed till 31.10.2021 i.e. upto one year from the pan-India launch of FoSCoS on 01.11.2020. Further, mandatory modification with fee of Rs. 1000 was allowed till 31.03.2022 vide order of even number dated 27th December 2021 [copy enclosed].

- 2. Similarly, FSSAI vide order number 15(31)2020/FoSCoS/RCD/FSSAI dated 16th September 2021 issued directions for State Licensed Manufacturers of Nutraceuticals and other related products to mandatorily migrate to Central License category by 31.12.2021. Further, mandatory migration by such State Licensed Manufacturers was extended till 31.03.2022 vide order of even number dated 27th December 2021 [copy enclosed].
- 3. As the last date for the mandatory modification/migration of the old methodology licenses will be over on 31.03.2022, such Food Business Operators [FBOs] will not be allowed to file renewal of FLRS licenses wef 01.04.2022. If an FBO wants to renew their existing license w.e.f 01.04.2022, he/she has to follow below Standard Operating Procedure [SOP]:
 - a. Only if the validity of license is remaining, FBOs can get their old methodology license [initially granted from FLRS portal] modified to Standardised Product Selection methodology of FoSCoS or can migrate from State License for Manufcturing of Nutraceuticals and other related products to Central License by way of modification within the validity period of license.
 - b. Only FBOs who have modified their license as per point (a) above, will be allowed to file application for renewal of their license on FoSCoS.
- 4. This issues with the approval of the Competent Authority.

Enclosure: As stated above

(Inoshi Sharma) Executive Director (CS) Email: ed-office@fssai.gov.in

To -

- 1. All Food Business Operators, Associations, Food Safety Mitra and other Stakeholders
- 2. Commissioner of Food Safety of all States/UTs and Directors of all Regional Offices, FSSAI
- 3. CTO, FSSAI for uploading on website

- 1. All Divisional Heads of FSSAI
- 2. PPS to Chairperson, FSSAI
- 3. PS to CEO, FSSAI

File No.: 15(31)2020/FoSCoS/RCD/FSSAIpt9

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety & Standards Act, 2006)

(Regulatory Compliance Division) FDA Bhawan, Kotla Road, New Delhi-110002

Dated, the 27 December, 2021

ORDER

Subject: Extension of period for modification/migration of License by existing FSSAI Licensed Manufacturers - reg.

Reference to following FSSAI Orders:

- (i) FSSAI Order of even number dated 16th June, 2021 regarding mandatory modification of license by existing FSSAI Licensed Manufacturers as per the new methodology for Standardised Product Selection in FoSCoS till 31st December, 2021 (Copy enclosed).
- (ii) FSSAI Order of even number dated 16th September, 2021 regarding mandatory migration of State License into Central License by Manufacturers of 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 (Copy enclosed).
- With the approval of the Competent Authority, it has been decided to extend the 2. last date for mandatory modification/migration of license as per the above said orders from 31st December 2021 to 31st March, 2022, beyond which FBOs who do not get their license modified/migrated, shall not be able to apply for renewal of license.

Enclosure: As stated above

Yours Sincerely,

Executive Director (CS)

Email: ed-office@fssai.gov.in

To.

- 1. All Food Businesses Operators, Associations, Food Safety Mitra and Other Stakeholders
- 2. Commissioner of Food Safety of all States/ UTs
- 3. Directors of all Regional Offices, FSSAI
- 4. CITO to upload on FSSAI's website

- 1. PPS to Chairperson, FSSAI For information
- 2. PS to CEO, FSSAI For information

File No. 15(31)2020/FoSCoS/RCD/FSSAI

Food Safety and Standards Authority of India (A Statutory Authority established under the Food Safety & Standards Act, 2006)

(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi-110002

Dated, the LJune, 2021

ORDER

Subject: Extension of period for modification of License by Existing FSSAI Licensed Manufacturers without modification fee-reg.

Reference FSSAI order dated 29th October, 2020 regarding modification of license by existing FSSAI Licensed Manufacturers without modification fee till 30th June 2020 (Copy enclosed).

- 2. With the approval of the competent authority, it has been decided to extend the period for modification of license by existing FSSAI licensed Manufacturers without any modification fee till 31st October, 2021.
- 3. Further, it has been decided that such FSSAI Licensed Manufacturers who do not modify license by 31st October 2021, shall be permitted to apply for modification of their FSSAI license with fee up to 31st December, 2021. Thereafter, no modification of License would be permitted wef 1st January, 2022.
- 4. FSSAI Licensed Manufacturers shall not be permitted to apply for renewal of their license wef 1st January, 2022 in case of non-compliance with this order.
- 5. This issues with the approval of the competent authority.

Yours sincerely,

(Inoshi Sharma)

Executive Director (CS)

Email: ed-office@fssai.gov.in

To,

- 1. All Food Businesses Operators, Associations, Food Safety Mitra and other stakeholders
- 2. Commissioner of Food Safety of All States/ UTs
- 3. Directors of all Regional Offices, FSSAI
- 4. CITO- to upload on FSSAI's website

- 1. PPS to Chairperson, FSSAI- For information
- 2. PS to CEO, FSSA1 For information
- 3. Head (RCD)

No. 15(31)2020/FoSCoS/RCD/FSSAI

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety and Standards Act, 2006)

(Regulatory Compliance Division)

FDA Bhawan, Kotla Road, New Delhi - 110002

Dated, the 29 October 2020

Order

Subject: Extension of period for Modification of License by Existing FSSAI Licensed Manufacturers without modification fee - reg.

Reference FSSAI order of even number dated 28th May 2020 regarding modification of license by existing FSSAI Licensed Manufacturers without modification fee till 31st December 2020 (copy enclosed).

- 2. Consequent to the approval of Food Authority in its 31st meeting held on 20th October, 2020, it is informed that the period for modification of license by existing FSSAI Licensed Manufacturers, without any modification fee is extended till 30th June 2021.
- This issues with the approval of Comptent Authority in exercise of the powers vested under Sections 18(2)(d) and 16(5) of Food Safety and Standards Act, 2006.

Enclosure: As stated

(Parveen Jargar) Joint Director (RCD)

Tel No: 011-23237433

To-

- 1. All Food Business Operators, Associations, Food Safety Mitra and other Stakeholders
- 2. Commissioner of Food Safety of concerned States/UTs
- 3. Directors of all Regional Offices, FSSAI
- 4. Head (IT) for uploading on website

- 1. All Divisional Heads of FSSAI
- 2. PPS to Chairperson, FSSAI
- 3. PS to CEO, FSSAI

No. 15(31)2020/FoSCoS/RCD/FSSAI

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety and Standards Act, 2006)

(Regulatory Compliance Division) FDA Bhawan, Kotla Road, New Delhi - 110002

Dated, the 28th May, 2020

ORDER

Subject: Modification of License by Existing FSSAI Licensed Manufacturers upon launch of FoSCoS- reg.

The Food Authority in its meeting held on 6th November 2019 had approved the proposal regarding mapping of Standardized Food Products with Food Category System for the purpose of licensing and registration of manufacturers. Consultation paper on the proposal was prepared, circulated and uploaded on FSSAI website on 17.12.2019 for comments and suggestions. The comments received have been thoroughly examined and wherever needed, Standards Division, FSSAI has been consulted to finalize the mapping of Standardized Food Products with Food Category System. The documents on finalized mapping and the methodology for clubbing of various products under one group are available on www.foscos.fssai.gov.in.

- 2. The key features of the selection based approach for Standardised Products while applying for FSSAI License (only for Manufacturers/Processors) are as below:
 - a) At present, while applying for license in FSSAI's online system i.e. Food Licensing and Registration System (FLRS https://foodlicensing.fssai.gov.in), the manufacturer applicant types the name of food product he intends to manufacture in the text box provided. It replaces the text box approach with selection options for standardised food products, with the launch of Food Safety Compliance System (FoSCoS https://foscos.fssai.gov.in).
 - b) The change is only for manufacturer (including re-packer, re-labeller) of food products. Manufacturer will have to select a standardized product only out of list provided on the licensing platform. The standardised product shall have its classification as per food category system indicated for convenience. In case, not falling under standardized product, FBO will have to apply under Proprietary Food, Non specified Food or Supplements/Nutraceuticals as the case may be. In these cases, text box approach will continue. Licensing for all KoBs other than manufacturer, such as catering (food services), transporter, wholesaler, storage, e-Commerce etc will continue to be on the basis of broad food product categories.
 - c) Category 99 is a residual category for licensing purpose for products such as additives/processing aids/enzymes etc. It is proposed to continue the text box approach for category 99 as while some Food Additives & other substances have standards, there are many for which standards are under development. At an appropriate time in future, this category may also be considered to be moved to Standardised list approach.

- d) A new Category 100 is being created only for the purpose of licensing, wherein standardised products do not have Food Category System mapped, will be listed.
- e) Under the Food category 15.0 -Ready to eat Savouries and 16.0 Prepared Food, there are no standardized food products; hence a manufacturer (say of ready to eat packets) needs to take central licence under Proprietary Food Category.
- f) Many manufacturers who have licences in wrong food category or have license for nonstandardized products as standardized food products in previous system, will be required to get their license modified.
- g) In case of existing FBOs holding valid licenses for manufacturing of food products, they shall be required to modify their existing license upon migrating to new system i.e. FoSCoS (https://foscos.fssai.gov.in) by selecting the products from available list of standardised products. A window for modification of license, without any modification fee has been provided to such licensed manufacturers for period upto 31st December 2020). Further, before such product migration to standardised products list, if their renewals of licenses get due, then renewal window for only one year will be provided once instead of 1-5 years as specified in FSS (Licensing and Registration of Food Businesses) Regulations, 2011.
- This issues with the approval of Competent Authority in exercise of the powers vested 3. under sections 18(2)(d) and 16(5) of Food Safety and Standards Act, 2006.

Encl: As stated

(Dr Shobhit Jain)

Executive Director (Compliance Strategy)

Email: ed-office@fssai.gov.in

To

- 1. All Food Business Operators involved in Manufacturing/Processing of Food Products
- 2. Commissioner of Food Safety of all States/UTs and all Central Licensing Authorities

3. CITO, FSSAI: For uploading on FSSAI website.

- 1. Head (RCD)
- 2. PPS to Chairperson, FSSAI
- 3. PS to CEO, FSSAI

File No. 15(31)2020/FoSCoS/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 Food Safety Compliance System (https://foscos.fssai.gov.in)

Dated, the. J.L. September, 2020

Order

Subject: Food businesses manufacturing 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 to be covered under the purview of Central Licensing Authorities-reg.

At Present, the food businesses operators (FBOs) manufacturing 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 hereinafter referred to as 'Nutraceutical Regulations' are being licensed by the State as well as the Central Licensing Authorities under the General manufacturing i.e. FBOs having production capacity of 2MT per day are eligible for State License while FBOs having production capacity of more than 2MT per day are eligible for Central License.

- 2. Now Considering the complexity and sensitivity of the products covered under the Nutraceutical regulations and of the products covered under it, it has been decided with the approval of the Food Authority to license food businesses manufacturing products covered under the said regulations through Central Licensing Authorities only, irrespective of turnover of the FBOs. Henceforth, the Central License option shall be available for manufacturers of food products covered under Nutraceutical regulations.
- 3. Accordingly, all existing State Licensed FBOs having license for the food products 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 shall migrate to Central License with a modification fee of Rs. One Thousand [Rs. 1000] only and the payment of the differential amount between State License fee and Central License fee for remaining number of complete years of validity of their existing licenses by 31st December 2021. Further, State Licensed FBOs manufacturing products under Nutraceutical Regulations shall not be able to apply for renewal of their license after 31st December 2021.
- 4. All existing applications for new/modification licenses [under processing] with State Licensing Authorities shall stand rejected and fee paid shall be refunded to the concerned FBOs in such cases. Such FBOs shall be required to resubmit the application with full fee to the concerned Central Licensing Authorities.

- 5. It is further informed that FSSAI has already enabled food businesses to migrate/modify their licenses from State License to Central License without change in existing license number w.e.f 1st June 2021, thereby facilitating food businesses to save overhead costs and undue hassle which otherwise, might have occurred due to change in existing license number and subsequently loss of pre-printed packaging material, if any.
- 6. This issues with the approval of the Competent Authority.

Yours sincerely,

(Inoshi Sharma)
Executive Director (CS)
Email: ed-office@fssai.gov.in

To-

- 1. All Food Business Operators, Associations, Food Safety Mitra and other Stakeholders
- 2. Commissioner of Food Safety of concerned States/UTs
- 3. Directors of all Regional Offices, FSSAI
- 4. Head (IT) for uploading on website

- 1. All Divisional Heads of FSSAI
- 2. PPS to Chairperson, FSSAI
- 3. PS to CEO, FSSAI