

Voluntary Report – Voluntary - Public Distribution

Date: November 08, 2023

Report Number: IN2023-0078

Report Name: India's FSSAI Re-Operationalizes Labeling and Display Regulations

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report

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Report Highlights:

On October 17, 2023, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified Direction STD/SP-08/A1.2022/N-01-Part (1). The directive indicates that the DRAFT Food Safety and Standards (Labeling and Display) Amendment Regulations (2022) in its final form will be delayed for the foreseeable future. The FSSAI, with a July 1, 2023, date, is re-operationalizing the provisions specified in its earlier directive of January 6, 2023, on this subject.

DISCLAIMER: The information contained in this report was retrieved from the Food Safety and Standards Authority of India's (FSSAI) website <http://www.fssai.gov.in>. The Foreign Agricultural Service (FAS) Office of Agricultural Affairs at the U.S. Embassy in New Delhi, USDA, and/or the U.S. government make no claim of accuracy or authenticity. The Government of India has not officially endorsed this report. Import approval for any product is subject to local rules and regulations as interpreted by Indian officials at the time of product entry. [Note: Use Google Chrome to access the links that do not open in Microsoft Edge. Indian host sites will geo-block site access on a rolling basis].

GENERAL INFORMATION

On October 17, 2023, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified on its public website, **Direction STD/SP-08/A1.2022/N-01-Part (1)** (see, Appendix I).

The new FSSAI direction states that the DRAFT **Food Safety and Standards (Labeling and Display) Amendment Regulations (2022)** in its final form will be delayed for the foreseeable future. The FSSAI, with a July 1, 2023, date, is re-operationalizing the provisions specified in its earlier directive of January 6, 2023, on this subject.

The earlier draft regulations (2022) include labeling requirements for non-retail containers, minimally processed products such as wheat, rice, cereals, pulses, fruits, vegetables and/or products that contain a single ingredient, tolerance limits for certain food products. These also include a warning statement pertaining to *Pan Masala*.¹ (See, [GAIN-INDIA | IN2023-0003 | India's FSSAI Rolls Out Re-Operationalized Labeling and Display Regulations](#)).

The full text of the FSSAI **Direction STD/SP-08/A1.2022/N-01-Part (1)** is accessible on the FSSAI website located at:

[https://fssai.gov.in/upload/advisories/2023/10/652e486774a40Direction%20regarding%20reoperationalization%20of%20draft%20FSS Labelling%20and%20Display amendment%20regulations,%202022.pdf](https://fssai.gov.in/upload/advisories/2023/10/652e486774a40Direction%20regarding%20reoperationalization%20of%20draft%20FSS%20Labelling%20and%20Display%20amendment%20regulations,%202022.pdf).

¹ Pan (*paan*) masala (PM) is a mixture made from the areca nut (commonly referred to as betel nut and/or supari), lime, catechu (*kattha*) (an extract of the acacia tree used as a food additive, astringent, tannin, and dye), and flavoring agents. The areca nut is highly addictive and carcinogenic. The International Agency for Research on Cancer (IARC) has identified betel quid itself, with (PM-T) or without tobacco, as a group I carcinogen. The use of the Areca nut in any form causes oral cancer in humans. The U.S. Food and Drug Administration (FDA) does not have regulations specific to areca nut, but it does regulate the areca nut as an imported food and/or, when mixed with tobacco, as a tobacco product. See, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8192186/#:~:text=The%20International%20Agency%20for%20Research,areca%20nut%20chewers%20%5B37%5D>.

APPENDIX I: INDIA, FSSAI DIRECTION ON RE-OPERATIONALIZATION OF FOOD SAFETY AND STANDARDS (LABELING AND DISPLAY) REGULATIONS

File No: STD/SP-08/A1.2022/N-01-Part(1)

Food Safety and Standards Authority of India

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

(Regulation division)

FDA Bhawan, Kotla Road, New Delhi-110002

Dated, the 17th Oct, 2023

Subject: Direction under Section 16 (5) of Food Safety and Standards Act, 2006 regarding re-operationalisation of Food Safety and Standards (Labelling and Display) Amendment regulations 2022 related to Labelling Requirements of non-retail container, minimally processed food, tolerance limit, warning statement related to pan masala etc. -reg.

In exercise of the power conferred under section 92 of the *Food Safety and Standards Act, 2006*, FSSAI has framed draft *Food Safety and Standards (Labelling and Display) Amendment Regulations 2022* and the same were operationalised *vide* direction STD/SP-08/A1.2022/N-01-Part (1) dated 17.06.2022 and re-operationalized *vide* direction STD/SP-08/A1.2022/N-01-Part (1) dated 06.01.2023.

2. The draft Food Safety and Standards (Labelling and Display) Amendment Regulations 2022 were also notified on 30.11.2022 for inviting comments from stakeholders and are now under the process for finalization. As the notification of final amendment regulation is likely to take some time, it has been decided to re-operationalize the provisions specified in the directions dated 06.01.2023, with effect from **01.07.2023**.

3. This issues with the approval of the Competent Authority in exercise of the powers vested under Section 18 (2) (d) read with 16 (5) of *Food Safety and Standards Act, 2006*.

Encl: Direction dated 06.01.2023


(Dr. Amit Sharma) 17/10/23

Director
Regulation and S&S Division
FSSAI, New Delhi

File No: STD/SP-08/A1.2022/N-01-Part (1)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(Regulation division)
FDA Bhawan, Kotla Road, New Delhi-110002

Dated, the 6th January, 2023

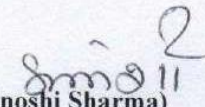
Subject: Direction under Section 18 (2)(d) read with Section 16 (5) of Food Safety and Standards Act, 2006 regarding re-operationalisation of Food Safety Standards (Labelling and Display) Amendment regulations 2022 related to Labelling Requirements of non-retail container, minimally processed food, tolerance limit, warning statement related to pan masala etc. –reg.

In exercise of the power conferred under section 92 of the *Food Safety and Standards Act, 2006*, FSSAI has framed draft *Food Safety and Standards (Labelling and Display) Amendment Regulations 2022* and the same were operationalised vide direction STD/SP-08/A1.2022/N-01-Part (1) dated 17.06.2022.

2. These draft Food Safety and Standards (Labelling and Display) Amendment Regulations 2022 were also notified on 30.11.2022 for inviting comments from stakeholders within a period of 60 days. Accordingly, finalization of these draft regulations based on the comments received, and publication of the final amendment regulations after legal vetting / approval is likely to take some more time.

3. Therefore, the provisions of these draft amendment regulations as enclosed (Annexure) are hereby re-operationalized with effect from 01.01.2023.

4. This issues with the approval of the Competent Authority in exercise of the powers vested under Section 18 (2) (d) read with Section 16 (5) of *Food Safety and Standards Act, 2006*.


(Inoshi Sharma)
Executive Director (C S)

Notice for operationalization of draft Food Safety and Standards (Labelling and Display) Amendment Regulations, 2022.

Food Safety and Standards Authority of India, hereby makes the following regulations operational with effect from 01.01.2023.

1. These regulations may be called the Food Safety and Standards (Labelling & Display) Amendment Regulations, 2022.

2. In the Food Safety and Standards (Labelling & Display) Regulations, 2020 (herein after refer as said regulations), -

(1) in sub-regulation (3) of regulation 5,

(a) in clause (b), after the proviso starting with 'provided that' and ending with "nutrients on the label" the following shall be inserted namely, -

"Provided further that per serve percentage (%) contribution to RDA and number of servings per pack may not be given for Infant Nutrition products as defined under Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020."

(b) in clause (c),

i. item (i) shall be substituted with the following, namely, -

"(i) Raw agricultural minimally processed products such as wheat, rice, cereals, pulses, fruits and vegetables and/or products that comprise a single ingredient.

Explanation: Minimally processed foods are the ones that are slightly altered for the main purpose of preservation but which do not substantially change the nutritional content of the food. This may involve cleaning and removing inedible or unwanted parts, grinding, refrigeration, pasteurization, fermentation, freezing, and vacuum-packaging."

ii. item (ii) shall be omitted.

iii. item (xiii) shall be substituted with the following, namely, -

"(xiii) Health supplements, Nutraceuticals and Foods for Special Dietary Uses (FSDU) in tablet and capsule format, with respect to macronutrients, when sources of energy are insignificant."

(c) Clause (d) shall be substituted with following, namely, -

"(d) The compliance to quantity of declared nutrients on the label shall have the tolerance of ± 20 percent of the value for that nutrient declared on the label at any point in time within declared shelf life of the product."

(2) In regulation 8,

(a) after clause (1)(a) the following shall be inserted, namely, -

“(1)(b) The logos notified under Food Safety & Standards Regulations may not be given where the surface area of the package is not more than 100 square centimetres, but this information shall be given on the multi-unit packages.”

(3) In Chapter-4, regulation 10, shall be substituted with the following namely, -

“10. Labelling Requirements of non-retail container

(1) Every packaged food meant for non-retail sale shall provide the following mandatory information either on the container or pasted on the label thereto:

- (a) Name of the food;
- (b) FSSAI Logo and License number;
- (c) Date marking and storage instructions, when required for the safety or integrity of the product;
- (d) Lot No. /Batch No. /Code No and
- (e) Name and address of the manufacturer or packer (including country of origin for imported packages).

provided that in case of Non-retail container containing multiple types of food, the mandatory information shall be provided for all the types of foods contained therein.

provided that non-retail container, which provides access to all the information required by sub-regulation 10(1) on the label of pre-packaged foods within the non-retail container, the information stipulated in sub-regulation 10(1) is not required.

(2) The following information if not provided on the label shall be provided in the accompanying documents:

- (a) List of ingredient;
- (b) Declaration regarding Veg or Non-Veg and
- (c) Net Quantity.

provided that the information required under sub-regulation 10(2) shall be traceable to the food in non-retail container.

provided that if all information required under sub-regulation 10(2) is made available on the label of non-retail container or pre-packaged foods within the non-retail container, sub-regulation 10(2) does not apply.

In the case of a non-retail container used as a food transportation unit that is not amenable to possess a label, all the information required under sub-regulation 10(1) & 10 (2) shall be provided in the accompanying documents or through appropriate other means (e.g. electronically between food businesses) and shall be effectively traceable to the food in such containers.

(3) The following labelling requirements are exempted if they are provided in a Barcode/Global Trade Identification Number (GTIN); -

- (a) Address of the brand owner whether or not, he himself is the manufacturer, marketer, packer or bottler, as the case may be and
- (b) the license number of the manufacturer or marketer or packer or bottler, as the case may be, if different from the brand owner.

(4) Every package meant for non- retail sale shall be clearly identifiable as such. If the container is not clearly identifiable as a non-retail container, the container shall:

- a. bear a statement to indicate that the food is not intended to be sold directly to the consumer or to clearly identify it as a non-retail container. Some examples of such statements are:

“NON-RETAIL CONTAINER”

“NON-RETAILCONTAINER - NOT FOR DIRECT SALE TO CONSUMER”

OR,

- b. carry any other mark that indicates that the container is not intended to be sold directly to the consumer.

(5) General Information:

(a) Information and the statements required to appear on the label by virtue of this Standard or any other Standards shall be clear, prominent, readily legible and applied in such a manner that any tampering with it will be evident.

(b) The mandatory information required on the label under sub-regulation 10 (1) shall appear in a prominent position on the non-retail container and shall be readily accessible under normal handling and use of the container.”

(4) in Schedule I, for the paragraph (1) following shall be substituted namely, -

“(1) Every package of food fortified as per FSS (Fortification of Foods) Regulations, 2018, shall carry the words “fortified with (name of the fortificant)” and the logo, as specified below, on the label. It may also carry a tag line “Sampoorna Poshan Swasth Jeevan” under the logo.”

(5) in Schedule II,

- a. in paragraph 1, in sub paragraph (3), in the table,

- i. for S. No. 1, the following shall be inserted, under column “Declarations”, namely, -

“Note: This warning statement should be clearly legible/audible in advertisements related to Pan Masala”.

- ii. for S. No. 3, under column “Declarations, point (iv) following shall be substituted namely, -

“(iv) Not recommended for phenylketonurics; for children; pregnant or lactating women (in case of Aspartame-Acesulfame salt or admixture/combination of Aspartame & Acesulfame Potassium)”

- b. in paragraph 1, in sub paragraph (4), in table,

- i. for S. No. 1, under column "Declarations", point (iv) the following shall be substituted namely,
-
“(iv) Not recommended for phenylketonurics; for children; pregnant or lactating women (in case of Aspartame-Acesulfame salt or admixture/combination of Aspartame & Acesulfame Potassium)”
- ii. for S. No. 2, under column "Declarations", after the proviso starting with 'provided that' and ending with "in the mixture", the following proviso shall be inserted, namely, -
“Provided further that the repetition of information may not be required for combination of sweeteners.”
- c. The words “pregnant and lactating mothers”, wherever it appears, shall be substituted with the following namely, -
“pregnant or lactating women”.

Attachments:

No Attachments.