

F. No. SS-T010/1/2023-Standard-FSSAI-Part(1)  
**Food Safety and Standards Authority of India**  
(A Statutory Authority established under Food Safety and Standards Act, 2006)  
FDA Bhawan, Kotla Road, New Delhi- 110002

Dated, the 25<sup>th</sup> September, 2023

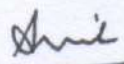
**Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding re-operationalisation of Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations with respect to the standards of Fortified Rice Kernel**

In exercise of the power conferred under Section 92 of the Food Safety and Standards Act, 2006, FSSAI had framed the Draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations with respect to the standards of Fortified Rice Kernel (FRK), Vitamin & Mineral Premix for FRK and Rice Flour used for making FRK and the same were draft notified in the Gazette of India on 25.05.2022.

2. The draft standards were operationalized *vide* direction dated 23.06.2022 and later re-operationalised with effect from 23.12.2022 *vide* direction dated 11.04.2023. The provisions in the draft amendment regulations are in the process of final notification which is likely to take further more time for finalization & publication in the Gazette of India. Meanwhile, to strengthen the National level fortification programme and its implementation, it has been decided to again re-operationalise the provisions for Fortified Rice Kernel (FRK), Vitamin & Mineral Premix for FRK and Rice Flour used for making FRK as specified in the direction (no. SS-T010/1/2023-Standard-FSSAI) dated 11.04.2023, with effect from 23.06.2023 for a period of 6 months or until final notification of *ibid* draft regulations whichever is earlier.

3. 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.

*Encl: Copy of directions dated 11.04.2023 & 23.06.2022*

  
(Dr. Amit Sharma)  
Director  
Regulation and S&S Division  
FSSAI, New Delhi

To:

1. ED(CS)-with a request to communicate to Food Safety Commissioners of all States/UTs and all Regional Directors, FSSAI
2. Director (TICD)-with a request to communicate to all Authorized Officers

Copy to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. Head (S&S)
4. Advisor (QA)
5. CITO, FSSAI-with a request to upload the direction on the FSSAI website

F. No. SS-T010/1/2023-Standard-FSSAI  
**Food Safety and Standards Authority of India**  
(A Statutory Authority established under Food Safety and Standards Act, 2006)  
FDA Bhawan, Kotla Road, New Delhi- 110002


Dated, the 11<sup>th</sup> April, 2023

**Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding re-operationalisation of Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations with respect to the standards of Fortified Rice Kernel**

In exercise of the power conferred under Section 92 of the Food Safety and Standards Act, 2006, FSSAI had framed the Draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations w.r.t the standards of Fortified Rice Kernel and the same were draft notified in the Gazette of India on 25.05.2022.

2. The draft standards were operationalized *vide* direction dated 23.06.2022. The provisions in the draft amendment regulations are in the process of final notification which is likely to take further more time for finalization & publication in the Gazette of India. Meanwhile, to strengthen the National level fortification programme and its implementation, it has been decided to re-operationalise the provisions for Fortified Rice Kernel (FRK), Vitamin & Mineral Premix for FRK and Rice Flour used for making FRK as specified in the direction (no. STD/FA/38/FSSAI) dated 23.06.2022 with effect from 23.12.2022. However, the provisions with respect to Yeast and Mould Count and Aerobic Plate Count parameter of 'Rice flour for preparation of Fortified Rice Kernel (FRK)' stand withdrawn from the date of issue of this direction.

3. 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.

  
(Dr. Amit Sharma)  
Director (Regulation)

To:

1. All Food Safety Commissioners
2. All Authorized Officers, FSSAI
3. All Central Designated Officers, FSSAI
4. CITO, FSSAI – for uploading on the website

Copy for information to:

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

भारतीय खाद्य सुरक्षा और मानक प्राधिकरण  
(खाद्य सुरक्षा और मानक अधिनियम, 2006 के तहत स्थापित एक वैधानिक प्राधिकरण)  
(विज्ञान एवं मानक प्रभाग)  
एफडीए भवन, कोटला रोड, नई दिल्ली- 110002


Dated, the 23<sup>rd</sup> June, 2022

**Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding operationalization of Draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations regarding the standards of Fortified Rice Kernel**

In exercise of the power conferred under Section 92 of the Food Safety and Standards Act, 2006, FSSAI had framed the Draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations w.r.t. the standards of Fortified Rice Kernel and the same has been draft notified in the Gazette of India on 25<sup>th</sup> May, 2022.

2. The above mentioned draft amendment regulations are in the process draft consultation from the stakeholders. Finalising the said amendment notification after considering the comments of stakeholders and its final notification in the Gazette of India are likely to take further more time. Meanwhile, to strengthen the National level fortification programme and its implementation, it has been decided to operationalize the provisions related to Fortified Rice Kernel of the above mentioned draft amendment, as provided in the **ANNEXURE-1**, with immediate effect.

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

  
(भास्कर, ऐन)

सलाहकार (विज्ञान एवं मानक)

To

1. ED(CS)-with a request to communicate to Food Safety Commissioners of all States/UTs
2. Advisor (QA)
3. Head (RCD)/Head (Regulations)/ Head (Legal)
4. Director (TICD)-with a request to communicate to all Authorized Officers
5. All Regional Directors, FSSAI
6. CITO, FSSAI-with a request to upload this clarification on FSSAI website

Copy to:

1. PPS to Chairperson, FSSAI,
2. PS to CEO, FSSAI,

**Notice for operationalization of draft Food safety and standards (Food Products Standards and Food Additives) Amendment Regulations, 2022 w.r.t Fortified Rice Kernel.**

The Food safety and standards Authority of India hereby, makes the following regulations operational with immediate effect from 22.06.2022.

1. These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2022.
2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in sub-regulation 2.4.6, after clause 24, the following clauses shall be inserted, namely. -

**24(a) Rice Flour for preparation of Fortified Rice Kernel (FRK)**

- (1) Rice flour used for preparation of fortified rice kernel shall be white to off white powder. It shall be free flowing with characteristic odour and no off odour. It shall be free from foreign matter.
- (2) Rice flour used for preparation of fortified rice kernel shall conform to the following standards-

S.No.	Requirement	Limit
1.	Particle size (%) (Not less than)	90% passes through 60 mesh
2.	Moisture % by mass, Not more than	14.0
3.	Acid insoluble ash, % by mass (on dry basis), Not more than	0.15
4.	Alcoholic acidity, % Not more than	0.18
5.	Uric Acid, mg/kg, Not more than	100.0
6.	Yeast and Mould Count (cfu/g)	$1 \times 10^2$
7.	Aerobic Plate Count (cfu/g)	$1 \times 10^4$

- (3) In addition to the above, rice flour used for preparation of fortified rice kernel shall comply with the provisions of Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011 as applicable.

**24(b) Vitamin-Mineral Premix for Preparation of Fortified Rice Kernel (FRK)**

- (1) Vitamin and Mineral Premix (VMP) is combination of micronutrients (vitamins and minerals) in desired proportion ready for use as fortificant in the manufacturing of fortified rice kernels.
- (2) Vitamin and Mineral Premix shall be free flowing powder without any lumps, made from food grade form of Vitamins and minerals and shall contain vitamins and minerals in specified proportions.
- (3) Vitamin and mineral premix shall be white to off white in colour with faint odour. It shall be easy to use and free from any objectionable or undesirable colour, odour and foreign matter.
- (4) Vitamin and mineral premix shall be manufactured in premises built and maintained under hygienic conditions.
- (5) Vitamin and mineral premix shall conform to the following physico chemical requirements-

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S.No.	Requirement	Limit
1.	Moisture % by mass, Not more than	11.0
2.	Particle size of micronized ferric pyrophosphate (D90particles), $\mu\text{m}$	1-3
3.	Yeast and Mould Count (cfu/g)	$1 \times 10^2$
4.	Aerobic Plate Count (cfu/g)	$1 \times 10^4$

- (6) Vitamin and mineral premix shall contain following chemicals, which shall be minimum 95% of stated value on the label in case of premix concentrate-
- Micronized ferric pyrophosphate or sodium iron (III) ethylene diaminetetraacetatetrihydrate (sodium ferredetate -NaFeEDTA);
  - Folic acid; and
  - Cyanocobalamine or hydroxycobalamine.
- (7) Vitamin and mineral premix may also contain following chemicals, which shall be minimum 95% of stated value on the label in case of premix concentrate-
- Zinc oxide (ZnO);
  - Retinyl palmitate;
  - Thiamine hydrochloride, or thiamine mononitrate;
  - Riboflavin, or riboflavin 5'-phosphate sodium;
  - Nicotinamide, or nicotinic acid; and
  - Pyridoxine hydrochloride.
- (8) In addition to the above, vitamin and mineral premix shall comply with the provisions of Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011

**24(c) Fortified Rice Kernel**

- Fortified Rice Kernels (FRK) are Rice shaped kernels containing vitamins and minerals produced through extrusion.
- Fortified rice kernels shall resemble the rice as closely as possible in final attributes and shall be free from off odour.
- Fortified rice kernels shall conform to the following physico chemical requirements-

S. No.	Requirement	Limit
1.	Moisture % by mass, Not more than	12.0
2.	Broken rice kernels, percent by mass, Not more than	1.0
3.	Foreign matter, percent by mass, Max	0.001
4.	Damaged Kernels including Heat- Damaged	Absent
5.	Discolored grains	Absent
6.	Chalky grains	Absent
7.	Admixture with any other grains including non-fortified rice	Absent
8.	Uric Acid, mg/kg, on mass basis, Not more than	100.0
9.	Yeast and Mould Count (cfu/g)	$1 \times 10^2$
10.	Aerobic Plate Count (cfu/g)	$1 \times 10^4$

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56193/2023/Standards-FSSAI The kernels shall also conform to the following requirements of fortificants-

S. No.	Micronutrients	Sources	Fortificants level for 1:50 blending ratio	Fortificants level for 1:100 blending ratio
1.	Iron, mg/100 g	Micronised Ferric pyrophosphate; or	140 - 212.5	280 - 425
2.		Sodium iron (III) ethylenediamine tetraacetate trihydrate (sodium ferredetate-NaFeEDTA)	70 - 106.25	140 - 212.5
3.	Folic acid, µg/100 g	Folic acid	375 - 625	750 - 1250
4.	Vitamin B12 µg/100 g	Cyanocobalamine or Hydroxycobalamine	3.75 - 6.25	7.5 - 12.5

In addition, fortified rice kernels may also be fortified with following micronutrients, singly or in combination, at the level given in the table below:

S. No.	Micronutrients	Sources	Fortificants level for 1:50 blending ratio	Fortificants level for 1:100 blending ratio
1.	Zinc, mg/100 g	Zinc oxide	50 - 75	100 - 150
2.	Vitamin A, µg RE/100 g	Retinyl Palmitate	2500 - 3750	5000 - 7500
3.	Thiamine, (Vitamin B1), mg/100 g	Thiamine hydrochloride or Thiamine mononitrate	5 - 7.5	10 - 15
4.	Riboflavin (Vitamin B2), mg/100 g	Riboflavin or Riboflavin 5'-phosphate sodium	6.25 - 8.75	12.5 - 17.5
5.	Niacin (Vitamin B3), mg/100 g	Nicotinamide or Nicotinic acid	62.5 - 100	125 - 200
6.	Pyridoxine (Vitamin B6), mg/100 g	Pyridoxine hydrochloride	7.5 - 12.5	15 - 25

**Note:** FRK with fortificant levels 1:50, or 1:100 shall comply with standards given at sub-clause (3) of clause 24(c).

- (5) In addition to the above, Fortified rice kernels shall comply with the provisions of Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011 as specified.
- (6) Fortified Rice Kernel shall only be sold for industrial purpose for manufacturing fortified rice. It shall neither be sold in loose form nor to be sold directly to the consumer.
- (7) Each package of Fortified Rice Kernel shall carry following statements-  
The Ratio in which FRK is to be blended with rice kernels "1:50 OR 1:100"  
'NOT TO BE CONSUMED AS AN INDEPENDENT PRODUCT'  
'NOT TO BE CONSTRUED AS SUBSTITUTE FOR RICE OR RICE FLOUR'

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