No. 36-5/2018-QCC (Part) (E: 377504)

Government of India Ministry of Consumer Affairs, Food & Public Distribution Department of Food & Public Distribution (Quality Control Cell) ****

> **Krishi Bhawan, New Delhi** Dated the 26th December, 2023

To,

The Secretary,

Subject: Standard Operating Procedure (SoP) for Quality Management Protocols for Fortified Rice Kernels (FRK) and Fortified Rice (FR)-reg.

In the suppression of a letter of even number dated 15.03.2022 on the subject cited above, it has been decided to revise the Standard Operating Procedure (SoP) for Quality Management Protocols for Fortified Rice Kernels (FRK) and Fortified Rice (FR).

2. Accordingly, in order to maintain the quality of Fortified Rice Kernels (FRK) and Fortified Rice (FR) and to provide good quality Fortified Rice to the beneficiaries, all stakeholders are advised to ensure strict compliance with the revised Standard Operating Procedure (SoP) enclosed herewith. The said SoP is applicable with immediate effect.

3. This issues with the approval of the Competent Authority.

Encl: As above

Yours faithfully 102 (Vishwajeet Haldar)

Deputy Commissioner (S&R) Tel: 011-23384784

Copy to:

- 1. The Senior PPS to the Secretary (F&PD), D/o Food and PD, Krishi Bhawan, New Delhi
- 2. The Senior PPS to the Secretary, Department of Expenditure, North Block, New Delhi
- 3. The PPS to the Secretary, Department of School Education, Shastri Bhawan, New Delhi

- 4. The PPS to the Secretary, Department of Women and Child Development, Shastri Bhawan, New Delhi
- 5. The CEO, FSSAI, New Delhi
- 6. The CMD, FCI, Barakhamba Road, New Delhi
- 7. The DG, BIS, Bahadur Shah Zafar Marg, New Delhi
- 8. The CEO, NITI Aayog, New Delhi
- 9. The PPS to AS&FA, Department of Food and PD, Krishi Bhawan, New Delhi
- 10. The PPS to AS (P&FCI), Sr. Economic Advisor, JS (BP&PD), JS (Impex &IC), AS (Storage &PG), Department of Food and PD, Krishi Bhawan, New Delhi
- 11. The MD, CWC, New Delhi
- 12. The DS (BP), DS (Policy-1), Director (PD), Director (Finance), DS (FCA.cs)
- 13. The President FRK, Association
- 14. The President, Rice Miller Association
- 15. The Development Partners: WFP/Microsave.NI/Path.
- 16. The Director (Technical), NIC with a request to post the same on Department's website.

(Vishwajeet Haldar)

Deputy Commissioner (S&R) Tel: 011-23384784

2/5

Revised Standard Operating Procedure (SoP) for Quality Management Protocols for Fortified Rice Kernels (FRK) and Fortified Rice (FR).

The level-wise details of the Standard Operating Procedure (SoP) are as under:

Level 1. Vitamin & Mineral Premix (VMP) manufacturer

1.1 The Vitamin & Mineral Premix (VMP) used for manufacturing Fortified Rice Kernel (FRK) should be strictly in accordance with the latest FSSAI guidelines/regulations.

Level 2: FRK Manufacturer

At the level of Fortified Rice Kernel (FRK) Manufacturer/ Supplier:

- 2.1 FRK manufacturers shall have a FSSAI License/registration.
- 2.2 FRK manufacturer should procure the Premix from FSSAI Licensed Premix Manufacturer/ Supplier.
- 2.3 The chemical compound of the vitamin and minerals (VMP), used in FRK production, should be in accordance with the latest FSSAI guidelines/Standard Operating Procedure for FRK Production.
- 2.4 Certificate of Analysis (CoA) is to be obtained from FSSAI notified laboratories. COAs must have QR code as prescribed by FSSAI containing the information of lab/testing so that the genuineness of the COAs can be checked by scanning.
- 2.5 FRK manufacturers shall maintain the batch wise records of COAs&of Vitamin-Mineral Premix (VMP) used in FRK production in physical format and s corresponding batch of FRK produced and shall upload test reports on web portal specified by FSSAI for complete audit trail, which can be accessed during the inspections, if required, by FCI, State Government, DFPD and other authorities.
- 2.6 FRK manufacture shall provide the batch wise COAs of FRK and corresponding batch of Vitamin and Mineral Premix(VMP) to the fortified rice millers while selling FRK.

Level 3: Rice Millers Producing Fortified Rice by Blending FRK with Conventional Rice

- 3.1 The rice miller should have a valid milling license as well as a valid license for processing of fortified rice under food category 6.0 of the Indian Food Categorization System (Food Safety & Standards Act, 2006).
- 3.2 The millers should procure FRK from FSSAI licensed/registered FRK manufacturers/Supplier.

- 3.3 Millers should have Blending Machine as per the latest standards prescribed by BIS *i.e.* IS 17854: 2022 with integrated packaging/bagging facility to ensure homogeneous blending of FRK at 1% of FR by weight.
- 3.4 Bags of fortified rice offered for procurement to the procuring agencies must comply with FOOD SAFETY AND STANDARDS (LABELLING AND DISPLAY) REGULATIONS, 2020 AND FOOD SAFETY AND STANDARD (FORTIFICATION OF FOOD) REGULATIONS 2020.
- 3.5 The rice millers shall keep record of CoAs for each consignment of FRK and VMP. Rice millers shall provide the CoA of the FRK batch used and CoA of corresponding Premix to the procuring agencies at delivery of each consignment/lot of fortified rice.
- 3.6 During the production of fortified rice, quality checks should be done through the Blending Efficiency Test (BET) conducted on an hourly basis and proper record should be maintained.

Level 4: Procurement of Fortified rice by FCI/ State Agencies:

At the time of Tendering/Empanelment and Formalizing Contract

4.1 FCI/ State Procuring Agencies should specify all pre-requisites including blending efficiency of FRK at 1% of FR by weight, CoA, FSSAI license etc. of rice millers in their Milling Agreement to ensure uniformity and ease the QA/QC protocols.

At the time of Sourcing Fortified Rice from the Millers

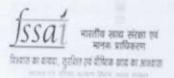
- 4.2 Fortified Rice consignments are to be checked for physical parameters by quality control personnel of procuring agencies/DFPD as per the existing procedure for analysis of food grains (IS:4333-2018 "*Methods of analysis for food grains*" with latest amendments).
- 4.3 The Tolerance Limit of Blending Ratio shall be as specified by the FSSAI vide communication dated 20.12.2023. For the purpose of uniformity, it is assumed that scenario 2 in Annexure 1 in the said letter shall be followed by the Rice Millers, wherein the mean value (Iron 3525 mg/kg; Folic Acid 10000 μ g/kg and Vitamin B12 100 μ g/Kg) of the prescribed range of micronutrients in FRK is expected to be ideal. In this scenario the range from -10% to +20 % i.e., 0.9 to 1.2 shall be permitted blending ratio.

However, if the sample fails on account of blending, an opportunity would be given to Rice Millers to bring the blending ratio of the rejected stock within any of the green footprints provided in Annexure-I either by adding FRK in FR or by

adding conventional rice in FR so that the blending ratio in the FR becomes acceptable.

- 4.4 The procuring agency should verify the CoAs of FRK, premix by scanning the QR code of CoA and check the blending ratio of FRK with conventional rice from the matrix of Blending ratio (placed at Annexure I)
- 4.5 At the time of acceptance of FR, Blending Ratio would be checked on a sample size of 50 Grams.
- 4.6 DFPD may conduct surprise checks to ensure the prescribed level of micronutrients in Fortified Rice at any stage mentioned above to address any complaints/grievance/references.

2022



फाइल सं. Std/SP-11/Misc/2023 भारतीय खाद्य संरक्षा एवं मानक प्राधिकरण (स्वास्थ्य एवं परिवार कल्याण मंत्रालय) (विज्ञान एवं मानक विभाग) एफडीए भवन, कोटला रोड. नई दिल्ली। 10002 -

ईमेल :sp-cereals@fssai.gov.in

दरभाष :011-23667208

To,

The Director

20th December, 2023

Department of Food & Public Distribution, Ministry of Consumer Affairs, Food and Public Distribution, Krishi Bhawan, New Delhi - 110001.

Subject- Tolerance limit for blending ratio of Fortified rice kernels and unfortified rice in preparation of fortified rice- reg.

Sir.

This is with reference to the letter received from Department of Food and Public Distribution (DoFPD) in respect to the Quality of Premix, Fortified Rice Kernel (FRK) & Fortified Rice (FR), where in it was requested to revisit the tolerance limit for blending ratio of Fortified rice kernels and unfortified rice in preparation of fortified rice. A matrix of three scenarios outlining the effect of various tolerance limits on the level of fortificants in Fortified Rice was also submitted (Annexure 1).

2. In this regard, the following observations were made:

- The matrix of three scenarios submitted considers the lower limit, mean value, and upper limit of the range of micronutrients specified for FRK in the FSSR. The compliance of these scenarios with the specified limits for micronutrients in fortified rice was evaluated, accounting for various deviations from the actual blending.
- It is observed that in scenario 2, where the mean value (Iron 3525 mg/kg; Folic Acid 10000 ii. µg/kg and Vitamin B12 100 µg/kg) of the prescribed range of the micronutrients in FRK is taken to consideration, the variations up to 20 % from the actual blending ratio would still meet the required level of micronutrients in the fortified rice as specified in the Fortification regulation.
- The statistical significance of the mean value serves to represent the typical value and is used ШĨ. as the central tendency of a numerical data set. The mean value of the prescribed limit of micronutrients in the FRK may be considered for blending ensuring that the final value of the micronutrients in the Fortified Rice falls within the limits prescribed in the Fortification regulation.
- Taking into account processing jurisprudence, manufacturers also aim to attain the mean value IV. of fortificants in FRK within a specified range of values.

3. In light of the above observations, it is informed that the FRK blending ratio of 1:50 or 1:100 as mentioned in the operationalized FSS (Food products Standards and Food Additives) standards is only a guideline/direction for the manufacturers. However, a variation of upto 20% on the higher side as stated in scenario 2, may not lead to a deviation from the range of fortificants in the fortified rice, as notified in FSS (Fortification of Foods) Regulation 2018.

Yours faithfully.

Dr. Kavitha Ramaswamy Joint Director, S&S FSSAI

Encl: As above

"सही भोजन, बेहतर जीवन"

Annexure 1

Blending Ratio for Matrix

Micronutrients	utrients Limits		Scenario 1	Scenario 2	Scenario 3	
	2800-					
Fe	4250	mg/kg	2800	3525	4250	
	7500-					
Folic Acid	12500	ug/kg	7500	10000	12500	
Vitamin B12	75-125	ug/kg	75	100	125	

Blending Ratio 0.9 1 1.1 1.2 1.3 1.4 1.5 1.6
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Scenario 1								
Fe	2520	2800	3080	3360	3640	3920	4200	4480
Folic Acid	6750	7500	8250	9000	9750	10500	11250	12000
Vitamin B12	67.5	75	82.5	90	97.5	105	112.5	120

Scenario 2								
Fe	3172.5	3525	3877.5	4230	4582.5	4935	5287.5	5640
Folic Acid	9000	10000	11000	12000	13000	14000	15000	16000
Vitamin B12	90	100	110	120	130	140	150	160

Scenrio 3								
Fe	3825	4250	4675	5100	5525	5950	6375	6800
Folic Acid	11250	12500	13750	15000	16250	17500	18750	20000
Vitamin B12	112.5	125	137.5	150	162.5	175	187.5	200