36-5/2018-QCC(Part)
Government of India,
Ministry of Consumer Affairs, Food & Public Distribution,
Department of Food & Public Distribution
(Quality Control Cell)

Krishi Bhavan, New Delhi
Dated: 15.03.2022

To,

The Secretary,
Food and Civil Supplies Department,
Government of ……..
(All States Government/ UT Administration)

Sub: Standard Operating Procedure (S.O.P) for Quality Management Protocols for Fortified Rice Kernels (FRK) and Fortified Rice (FR) -reg.

Madam/Sir,

I am directed to forward herewith Standard Operating Procedure (S.O.P) for Quality Management Protocols for Fortified Rice Kernels (FRK) and Fortified Rice (FR) formulated by the Department of Food and Public Distribution, in order to maintain the quality of Fortified Rice Kernels (FRK) and Fortified Rice (FR). Further, the State Governments may ensure strict compliance of the S.O.P so as to provide good quality Fortified Rice (FR) to the beneficiaries. The said SOP is applicable with immediate effect.

2. This issues with the approval of Secretary (F&PD).

Yours faithfully,

15/3/2022

(Vishwajeet Haldar)
Deputy Commissioner (S&R)
Tel: 23384784

Encl : As above

Copy to:-

1. PPS to Secretary (F&PD), Department of Food and PD, Krishi Bhawan, New Delhi.
2. Senior PPS to Secretary, Department of Expenditure,North Block, New Delhi.
3. PPS to Secretary, Department of School Education, Shastri Bhawan, New Delhi
4. PPS to Secretary, Department of Women and Child Development, Shastri Bhawan, New Delhi
5. The Director General, BIS, Bahadur Shah Zafar Marg, New Delhi.
6. The Chief Executive Officer, FSSAI,FDA Bhawan, New Delhi.
7. The Chief Executive Officer, NITI Aayog, New Delhi
8. PPS to AS & FA, Department of Food and PD, Krishi Bhawan, New Delhi.
9. PPS to JS (Policy & FCI)/ JS (BP &PD)/ JS (Storage)/ JS (Impex & IC)
10. The Chairman & Managing Director, Food Corporation of India, New Delhi.
11. Executive Director (QC), FCI HQ, New Delhi
12. All Executive Director (Zones), FCI.
13. Managing Director, CWC, New Delhi-for necessary action, please.
14. Director (P)/ Director (FCI)/Director (PD)/Director (Finance)
15. All QCC/IGMRI offices.
16. US (Py. I, II, III, IV)/US (FC A/c).
17. AD (S&I)/AD (QC)/AD (Lab).
18. Director (Technical), NIC with a request to put the information on the Ministry's website.

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

Background: To address the anemia and micronutrient deficiency in the country, Government of India approved the Centrally Sponsored Pilot Scheme on "Fortification of Rice & its Distribution under Public Distribution System. Further, the Department of Food and Public Distribution in consultation with Ministry of Women and Child Development and Department of School Education and Literacy has decided to scale up the distribution of fortified rice in all Integrated Child Development Scheme, (ICDS) and PM POSHAN (erstwhile MDM scheme) schemes from April 2021 in a phased manner leveraging domestic supply chain through Food Corporation of India (FCI)/State as the case may be.

Since both ICDS and PM POSHAN schemes cater to the vulnerable population of Women and Children, in view of this, it becomes of immense importance that the minimum threshold parameters fixed for quality standards of FRK should be in line with various levels under entire supply chain *i.e.* production to distribution. The ultimate objective is to curtail the chronic nutritional deficiencies.

The level-wise details on the SoP are as under:

Level 1: Production of FRK
At the level of Fortified Rice Kernel (FRK) Manufacturer/ Supplier:

1.1 FRK manufacturers should have FSSAI License/registration as well as quality certification such as ISO: 22000 etc.

1.2 Empanelment of FRK manufacturers may be done for an initial period of three years, which will be reviewed on a yearly basis by an independent third party.

1.3 FRK manufacturer should procure the premix for FRK production from the premix supplier/vendors having valid FSSAI license of 99.5 food categories as well as empanelled with FSSAI.

1.4 The FRK manufacturer may follow the standards as prescribed in United States pharmacopeia (USP) / IS / WFP – Technical Specifications for Micronutrient Powder etc till the time, the standards for vitamins and minerals premix are developed by FSSAI.

1.5 The chemical salt of the vitamin and minerals, used for FRK production, should be in line with the ones mentioned in FSSAI guidelines (Iron : Mecronized Ferric Pyrophosphate or Sodium Iron (III) Ethylene Diamine Tetra Acetate Trihydrate (Sodium feredetate - Na Fe EDTA); Folic Acid - Folic acid; Vitamin B_{12} - Cyanocobalamine or Hydroxycobalamine). All the premix material must be stored dry cool ventilated and hygienic conditions away from direct sun light.

1.6 The clean broken rice at an initial moisture content of 11-12% is ground to flour of particle size 60 or more than 60 mesh. The rice flour is very hygroscopic in nature, hence the raw material and final produce need to handle to control the moisture as per Good Manufacturing Practices (GMP) mentioned under Section II- "Technical Guidelines " of Pilot

Scheme for Fortification of Rice and its Distribution under Public Distribution System"/ Technical Hand-out on Fortification of Rice, FSSAI.

1.7 Potable water shall be used for mixing of ingredients (complying Indian Standards for Potable Water Standards IS 10500: 2012 with up to date amendments).

1.8 FSSAI approved emulsifiers / acid regulators / antioxidants shall be used as per the allowances prescribed in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

1.9 FSSAI, has been formulated Standard Operating Procedure (SoP) for Fortified Rice Kernels Production, the same should also be followed.

1.10 The level of micronutrients in FRK should have at least a middle/mean value as per Bureau of Standards (BIS) under IS 17782:2021 *"Fortified Rice Kernels-Specification". These levels as per present standards are:*

Iron - 3525 mg/kg

Folic Acid - 10,000 micro-gram/kg

Vitamin B 12 - 100 micro-gram/kg

1.11 Sanctity of the raw material/fortifiers/ingredients used for FRK production should be verified by the State Authorities/Food Safety Officers (FSO) on regular basis.

1.12 BIS approved equipment/machinery *via* IS 17853: 2022, *"Equipment for Manufacture of Fortified Rice kernel-Specification"* should be adopted by the FRK manufacturers to maintain the grain density, shape, size etc. In addition, Colour/texture to be aligned with the locally procured/consumed varieties in a particular State/Area.

1.13 The manufacturers will be given a time period of one (1) year to switch over from non-BIS to BIS certified machinery.

1.14 Certificate of Analysis (CoA) is to be obtained from an independent third party NABL accredited laboratory under section 43 of FSS Act 2006 and FSS Regulation, 2018.

1.15 FRK manufacturer will obtain a COA for each batch from an independent third party NABL accredited lab along with self certification. The batch may be defined based on the Quality Management System (QMS). The QMS should be in accordance with the FSSAI Manual on General Guidelines on Sampling- 2016.

1.16 FRK manufacturers will strictly maintain the records of COAs, other test records & FRK standardisation count/BET etc. A test check will be done to verify the self certification procedure adopted by FRK manufacturer (*format for self certification enclosed as Annexure*) **by S&R Division of DFPD. FCI may also test check these records at the time of procurement.**

1.17 All the standards/protocols specified under the operational guidelines of the pilot scheme should be in line at the end of empanelled FRK producers, before its delivery to the rice millers producing fortified rice.

Level 2: Blending of FRK with Conventional Rice
At the level of Rice Millers Producing Fortified Rice:
Pre-requisites:

2.1 The rice miller should have a valid milling license and a valid license for processing of fortified rice under food category 6.0 of Indian Food Categorization System (Food Safety & Standards Act, 2006).

2.2 The millers should procure FRK directly from, FSSAI licensed/registered FRK manufacturers.

2.3 Millers should have Automatic Blending Machine having the standards prescribed by BIS *i.e.* IS 17854: 2022 to ensure accurate blending at a ratio of 1:100.

2.4 FSSAI, has been formulated Standard Operating Procedure (SoP) for Fortified Rice Manufacturers, the same should also be followed.

2.5 Millers should get +F logo endorsed from FSSAI. All bags of fortified rice offered for procurement to the procuring agencies must bear blue coloured +F logo stencilled on it as well as on rexin slips. The offered lot of fortified CMR should be uniformly blended with FRK (1:100).

2.6 At the level of rice mill, QA/QC can be done through blending efficiency count.

2.7 The rice millers must ensure the receipt of CoA for each consignment of FRK obtained by FRK manufacturer by an independent third party FSSAI notified laboratory.

Testing of Quality Standards of Fortified Rice:
Qualitative testing:
2.8 During the production of fortified rice, quality checks should be done through blending efficiency counts conducted on hourly basis and proper record should be maintained.

Quantitative testing:

2.9 Rice millers should maintain batch wise record of FRK procurement and its usage for rice fortification as per CoA obtained from the FRK manufacturers.

2.10 In order to ensure that only good quality FRK is used for blending, the state procurement agency concerned may get random samples drawn directly from the fortified rice prepared by the mills and get them tested from any FSSAI approved NABL accredited labs.

2.11 Rice Millers will also be ensuring about packaging protocols of fortified rice as per FSSAI Packaging and Labelling Guidelines, related to packaging and Stencilling for proper identification of fortified rice stock.

2.12 Rice millers should make provisions for internal audit once in six month and external audit once in a year for maintaining the quality management system.

Level 3: Procurement of Fortified rice by FCI/ State Agencies as the case may be: At the time of Tendering/Empanelment and Formalising Contract

3.1 FCI/ State Agencies should specify all pre-requisites including blending ratio (1:100) of FRK with conventional rice, availability of CoA, validated FSSAI license of rice millers etc. in their tenders to ensure uniformity and ease the QA/QC protocols.

3.2 Procuring agency (FCI/State agency as the case may be) may use the range of (±)10% for blending efficiency for their operational ease.

3.3 A minimum of 10% samples may be referred to FSSAI approved NABL accredited labs to check the level of micronutrients on monthly basis by the procurement agencies *i.e.* FCI/State procurement agencies (as the case may be) before sending it for distribution under various social security schemes of GoI, within its shelf life.

At the time of Sourcing Fortified Rice from Millers

3.4 Fortified rice consignments are to be checked by the quality control personnel of procuring agencies/Ministry as per the existing procedure for analysis of food grains (BIS methods with latest version/up to date amendments).

3.5 All the responsibilities are lying with FCI, for the stocks delivered to agency.

3.6 For stocks procured by State agencies, the primary responsibility will be with the agency concerned. However, this aspect may be cross checked during the inspections to be conducted by Ministry and FCI as per Standard Operating Procedure (SOP) for inspection of DCP stocks.

3.7 The sourcing agency should check the blending ratio of each consignment at the time of acceptance to ensure that, whether prescribed quantity of FRK is blended with the conventional rice to make it fortified.

3.8 The fortified rice and FRK is separated physically and FRK is weighed/counted to check blending efficiency. In order to check blending efficiency, **sample size of 50 gms** is suggested to get a uniform result.

3.9 In case there is problem in physical separation, **a chemical test (Iron Spot Test)** may also be done to identify the number of FRKs in a test sample of fortified rice.

Secondly, to ensure that good quality FRK is used for blending, the FCI/State procurement agencies concerned may get random samples **(at least 10%)** drawn directly from the fortified rice prepared by the mills and get them tested from any FSSAI approved NABL accredited labs for micronutrient content on **monthly/quarterly basis** before sending its distribution under various schemes of GoI in a balanced and integrated manner to accomplish the nutritional gaps.

Moreover, all the provisions, which are defined and circulated on dated 16.07.2021 through the Standard Operating Procedure (SoP) for monitoring quality of foodgrains stocks procured under Decentralized Procurement (DCP) Scheme, will also be applicable.

Role of State/ District Authorities (Food Safety)

3.10 State oversight is necessary at every step of rice fortification. **District Collector will ensure the smooth implementation of the whole scheme.**

3.11 A proper milling agreement is to be executed between State Food Department and rice millers for milling of paddy with separate clause to be inserted regarding packaging/stenciling of **+F logo** on jute bag and rexin slip.

3.12 If the state agencies are involved in procurement of FRK, the same may be carried out by floating limited tenders or through GeM from any of the empanelled suppliers.

3.13 Use of FRK for blending with conventional rice may be permitted only upon validation of the CoA of FRK in terms of appropriate micronutrient levels and microbiological specifications by the officials of State/District Food & Civil Supply Department responsible for quality control.

3.14 State and District authorities should undertake random inspection visits at the rice mills to check if the rice miller is adhering to the QA/QC protocols and all documents are in line. The samples of fortified rice may also be lifted for analysis at FSSAI empanelled NABL accredited Labs.

Role of FSSAI (Food Safety Officers)

3.15 Food Fortification Resource Centre (FFRC) a unit of FSSAI, which is functioning as a resource hub for fortification will provide any kind of assistance to the FBO, Millers, States, FCI etc/facilitate training & capacity building (FBO's, rice millers, FPS owners, FSO's etc.) and monitor & evaluate the programme with support from development partners.

3.16 Mapping of NABL accredited labs under the states which may test the various quality parameters of FRK & FR.

3.17 Sampling from empanelled FRK manufacturers and rice millers for micronutrients analysis at least in each quarter.

3.18 The promotional and regulatory role of FSO may be as per the "Guidebook of Food Fortifications for Food Safety Officers".

3.19 Quality inspection visits should be made at the FRK manufacturing site, Rice mills during the production of FRK and fortified rice by the Food Safety Officer (FSO) employed with FSSAI.

3.20 The Food Safety Officer (FSO) should pick random samples from the mill and from fair price shops to ensure the quality of fortified rice (such that it covers all the shops and mills under his/her supervision in a quarter).

Other considerations for Sampling and testing fortified rice

3.21 Blending efficiency test should be performed every hour by preparing a composite sample. The composite sample should be collected from 10-15 bags randomly every hour during production and blending efficiency test should then be performed. Sample should always be taken before the weighment and stitching.

3.22 Composite samples should be sent to FSSAI empanelled NABL accredited labs for testing within a week of sample collection.

- As per Clause no. 2.4.1 of the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011, the sample shall be dispatched forthwith in the following manner:
    - The sealed container of one part of sample for analysis along with memorandum in Form VI shall be sent in a sealed packet to food analyst under appropriate condition to retain the integrity of the sample.
    - The sealed container of second and third parts of the sample and two copies of memorandum in Form VI shall be sent to Designated Officer by any suitable means.
    - The sealed container of the remaining fourth part of the sample and a copy of memorandum in Form VI shall be sent to an accredited laboratory along with fee prescribed by Authority, if so requested by the Food Business Operator, under intimation to the Designated Officer, provided that the fourth part also shall be deposited with Designated Officer if FBO does not request to send the sample to an accredited lab.

All other instructions/guidelines, mentioned under the operational guidelines of *Fortification of Rice and its Distribution under PDS* are also applicable on FRK manufacturers/Rice Millers/FCI/State agencies/FSSAI etc.

Annexure

Format for Self Assessment Certificate

Name of the Laboratory: _____

NABL Accreditation no.: _____ dated_____ Validity upto_____

FSSAI License no.: _____ dated_____ Validity upto_____

Name of Manufacturer:_____

FSSAI No._____

Address:_____

Contact no.:_____

Capacity: _____tons/hr.

Details of Sample:

i. Date of sampling: _____

ii. Date of Submission of sample:_

iii. Date of Analysis:_____

iv. Batch no.:_____

v. Representing Batch:_____

vi. Sample weight (gms):_____

Details of Testing:

(A)

Micronutrient	**Reference Range**	**Test Value**	**Reference Test method**	**Test method followed**
Iron (Micronized Ferric Pyrophosphate)	2800-4250 mg/kg		AOAC 944.02 or AACC 40-70.01 (Total iron present in ferric form by Atomic Absorption Spectroscopy or AOAC 984.27 (using ICP Emission))	
Folic Acid	7500-12500 µg/kg		AOAC 992.05 or EN 14131 (using microbiological extraction)	
Vitamin B12 (Cyanocobalamine or Hydroxycobalamine)	75-125 µg/kg		IS 16640	

(B)

Sl. No.	Physical attributes	Reference Range	Test Value	Reference Test method	Remarks
1.	Moisture Content %	12%		IS 4333(Part 2)	
2.	Broken Fortified Rice	1%		IS 4333(Part 1)	
3.	Foreign matter	0.001%		**IS 17782:2021**	
4.	Damaged grains	Absent		IS 4333(Part 1)	
5.	Discolored grains	Absent		IS 4333(Part 1)	
6.	Chalky grains	Absent		IS 4333(Part 1)	
7.	Admixture	Absent		IS 4333(Part 1)	
8.	Length (in mm)	-		-	
9.	Breadth (in mm)	-		-	
10.	Thousand kernel weight	-		-	
11.	True density	-		-	
12.	Prepared from (Raw/Parboiled) Rice				

Remarks: Best before_____

(Authorized Signature)

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