

F. No: 36-5/2018-QCC (Part)
Government of India
Ministry of Consumer Affairs, Food & Public Distribution
Department of Food & Public Distribution
(Quality Control Cell)

Krishi Bhawan, New Delhi

Dated 30.11.2022

To,

The Secretary,

Food and Civil Supplies Department,

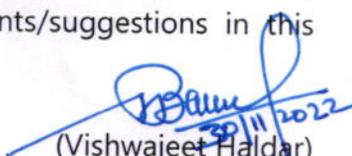
Government of.....

(All States Government/UT Administration).

Sub: Draft Operational Guidelines on Quality Control for Fortified Rice Kernels (FRK) and Fortified Rice (FR)-reg

Sir/Madam,

I am directed to forward herewith, draft Operational Guidelines on Quality Control for Fortified Rice Kernels (FRK) and Fortified Rice (FR) formulated by the S&R division under consultation with the various departments /organizations /stakeholders /developments partners. Further, it is once again requested to furnish the comments/suggestions, if any earlier or latest by 05.12.2022. If any comments / suggestions shall not be received within the prescribed time line, thereafter, it will be presumed that, the stakeholders have no comments/suggestions in this regards and department will finalize the same.


(Vishwajeet Halder)

Deputy Commissioner (S&R)

Tel: 23384784

Encl: As above.

Copy to:

1. The PPS to the Secretary (F&PD), Department of 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 DG, BIS, Bahadur Shah Zafar Marg, New Delhi.
6. The CEO, FSSAI, FDA Bhawan, New Delhi.
7. The CEO, NITI Aayog, New Delhi.
8. The PPS to AS&FA, Department of Food and PD, Krishi Bhawan, New Delhi.
9. The PPS to the AS (P&FCI), Sr. Economic Advisor, JS (BP&PD), JS (Impex &IC), JS (Stg &PG).
10. The CMD, FCI, 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.
16. The Director (Technical), NIC with request to host the same on department's website.

Operational Guidelines on Quality Control for Fortified Rice Kernels (FRK) and Fortified Rice (FR).

In pursuance of the announcement made by the Hon'ble Prime Minister in his address on the 75th Independence day, the Government of India has approved the supply of fortified rice throughout the Targeted Public Distribution System (TPDS) under the National Food Security Act (NFSA), Integrated Child Development Service (ICDS), Pradhan Mantri Poshan Shakti Nirman (PM POSHAN) and other welfare schemes (OWS) of Government of India in all states and Union Territories (UTs) in phase wise manner.

The overall objective of the scheme is to address the **anemia and micronutrient deficiencies reported in vulnerable sections of society**. Here, the Quality Control (QC) of Fortified Rice Kernel(FRK)/ Fortified Rice (FR) will play a major role in achieving the desired objectives. Further, all stakeholders involved in domestic food supply chain/social security programmes may be encouraged to ensure the quality standards of FRK & FR. To ensure that the quality product is produced and reaches to the Targeted Beneficiaries, it would require all the stakeholders to perform a proactive role in the entire ecosystem of rice fortification.

The detailed operational guidelines as mentioned below will act as a ready reference for all the stakeholders involved from production to distribution of FRK/FR throughout the country.

I. Quality Control at the level of Fortified Rice Kernel (FRK) Manufacturer/ Supplier:

- a) FRK manufacturers should have a valid FSSAI License /registration as well as quality certification such as ISO: 22000 etc.
- b) FRK manufacturer should procure the premix for FRK production from the premix supplier/vendors having valid FSSAI license of 99.5 food category as well as empanelled with FSSAI. They should also receive certificate of analysis (CoA) of the premix for micronutrient and microbiological levels adhering to FSSAI standards from FSSAI notified, NABL accredited labs, by the premix manufacturer/supplier. In addition, the details of the premix like the date of manufacturing, date of packaging, Date of expiry, etc. should be sought and recorded by the FRK manufacturer.
- c) The Standard Operating Procedure formulated by FSSAI for Fortified Rice Kernel production (issued during year 2022) may be strictly followed. In order to avoid micronutrient loss during procurement to distribution, the level of added micronutrients/fortificants should have at least the mean value of range suggested by FSSAI/BIS. FRKs to be blended with conventional rice in the ratio of 1:100 since all millers across the country have been trained and currently practicing the use of 1:100 blending ratio.
- d) Potable water shall be used for mixing of ingredients (complying Indian Standards for Potable Water Standards IS 10500: 2012 with up to date amendments).
- e) 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.
- f) The specifications of Rice Flour, Vitamins-Minerals premix for preparation of FRK & level of micronutrients in FRK should be as per the Food Safety Standards (Food Products, standards & food Additives) amendment regulation 2022.

- g) The raw material/fortificants/ingredients used in the manufacture of FRKs must comply the standards laid down in the draft FSSAI standards, June 2022. 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. The Food safety officer (FSO) will pick random samples from the manufacturer according to their sample plan for food products at monthly/quarterly intervals.
- h) 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 of FRK to be aligned with the locally procured/consumed varieties in a particular State/Area.
- i) Certificate of Analysis (CoA) of FRK is to be obtained from an independent third party FSSAI notified, NABL accredited laboratory under section 43 of FSS Act 2006 and FSS Regulation, 2018. The CoA of FRK must cover both microbiological and micronutrient parameters.
- j) FRK manufacturer will obtain a CoA for each batch from an independent third party FSSAI notified, 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. Along with CoAs, a 500 gm sample of FRK shall be dispatched to the procuring agency/rice miller prior to dispatch of FRK for use in rice mills. The procuring agency/rice millers may consider getting the FRK samples tested for microbiological and micronutrient parameters from FSSAI notified, NABL accredited labs. **The CoA of FRK should not be more than one month old at the time of delivery.**
- k) FRK manufacturers will strictly maintain the records of FRK standardization count, CoAs of FRK and Premix, quality checks for all raw material for parameters defined in draft FSSAI standards, June 2022.. 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.
- l) 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/ procuring agencies. The concerned batch of FRK delivered to rice mills must have at least 12 months of shelf life on the day of receipt of FRK..
- m) The finished products should not be stored directly on the floor. Preference for dispatch of FRK may be given to the FRK lots manufactured on earlier date. In addition, carton/boxes of vitamins and mineral premix should be stored in clean, dry place away from the sunlight. The boxes should be kept over the pallets or tarpaulin sheet and not directly over the floor.
- n) FRK manufacturer will ensure the packaging protocols of FRK as per the information required under the Legal Metrology (Packaged Commodities) Rules, 2011, and the Food Safety and Standards (Labelling & Display) Regulations, 2020.

II. Quality Control during production of Fortified Rice at Rice Mills :

- a) The rice miller should have a valid milling license and a valid FSSAI license/registration under food category 6.1 (Rice) of the Indian Food categorization system (Food Safety & Standards Act, 2006).
- b) The Standard Operating Procedure formulated by FSSAI for fortified rice manufacturer (issued during year 2022) may be strictly followed while manufacturing the fortified rice.
- c) The procuring agencies or millers should procure FRK from FSSAI licensed/registered FRK manufacturers only.
- d) The capacity building of rice millers/staff for BET test, Iron spot test, compliance of storage guidelines and maintenance of good hygienic and manufacturing practices, packaging & record keeping, etc., should be done prior to the commencement of fortified rice production.
- e) Rice millers should maintain batch wise record of FRK procurement (CoA of FRK and Premixes used in FRK, , date of manufacture of FRK, date of packaging, Best before date, etc.) and daily inventory of its usage for rice fortification as per records obtained from the FRK manufacturers.
- f) In order to ensure that only good quality FRK is used for blending, the procurement agencies concerned like FCI/State procurement agencies may get random samples drawn directly from the fortified rice prepared by the mills and get them tested from any FSSAI notified, NABL accredited labs as per validated method approved by FSSAI.**
- g) Rice Millers will also be ensuring about packaging protocols of fortified rice as per the information required under the Legal Metrology (Packaged Commodities) Rules, 2011, the Food Safety and Standards (Labelling & Display) Regulations, 2020 and the Food safety and standards (Fortification of foods) 1st Amendment regulations, 2021.
- h) 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.**
- i) 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. During the production of fortified rice, quality checks should be done through blending efficiency tests conducted on hourly basis and proper record should be maintained.
- j) 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 & regulatory instructions suggested by FSSAI from time to time. The offered lot of fortified CMR should be uniformly blended with FRK (1:100).**
- k) 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, +F logo endorsed by FSSAI, etc., in their tenders to ensure uniformity and ease of QC protocols.
- l) Procuring agency (FCI/State agency as the case may be) may use the range of (\pm)10% for blending efficiency test for their operational ease.

III. Quality Control at the level of agencies during Procurement/Sourcing of Fortified Rice From Millers

- a) 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 & FSSAI validated and approved methods).
- b) All the responsibilities are lying with agencies (FCI/State Government, etc.), for the stocks delivered to them. This aspect may be cross checked during the inspections to be conducted by the Ministry and FCI as per Standard Operating Procedure (SOP) for the inspection of DCP stocks.
- c) For Qualitative and Quantitative tests of fortified rice the provisions mentioned under Standard Operating Procedure on Quality Management protocols for Fortified Rice Kernels and Fortified Rice issued by the Government of India dated: 15.03.2022 shall be applicable.
- d) Additionally, all the provisions of the Standard Operating Procedure (SoP) for monitoring quality of food grains stocks procured under the Decentralized Procurement (DCP) Scheme, which have already been defined and circulated on dated 16.07.2021 will also be applicable.

IV. Quality Control at the level of State/ District Authorities (Food Safety)

- a) State and District authorities should undertake random inspection visits at the rice mills to check if the rice miller is adhering to the QC protocols and if all documents are in line as prescribed by Ministry, FSSAI & BIS. The samples of fortified rice may also be lifted for analysis at FSSAI notified, NABL accredited Labs.

Role of FSSAI

- a) The role of FSSAI shall be in accordance with the guidelines mentioned under Standard Operating Procedure on Quality Management protocols for Fortified Rice Kernels and Fortified Rice issued by the Government of India dated: 15.03.2022
- b) In addition to this, FSSAI may also address various qualitative and quantitative /technical/ regulatory/ promotional issues or doubts raised by the personnel's/individuals/FBOs/other stakeholders for smooth implementation of the scheme according to its mandate.

In addition to the above provisions, the Standard Operating Procedure on Quality Management protocols for Fortified Rice Kernels and Fortified Rice issued by the Government of India dated: 15.03.2022 shall also be applicable

Format for Self Assessment Certificate by FRK manufacturers/suppliers

Name of the Laboratory: _____

NABL Accreditation no.: _____ dated _____ Validity up to _____

FSSAI License no.: _____ dated _____ Validity up to _____

Name of Manufacturer: _____ **Details of Sample:**

FSSAI No. _____ i. Date of sampling: _____

Address: _____ ii. Date of Submission of sample: _____

Contact no.: _____ iii. Date of Analysis: _____

Capacity: _____ tons/hr. iv. Batch no.: _____

v. Representing Batch: _____

vi. Sample weight (gms): _____

Details of Testing:

(A) Levels per Kg of fortified rice

Micronutrient	Reference Range	Test Value	Reference 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	

Methods to be followed: FSSAI approved methods for determination of micronutrients i.e., FSSAI.FR.16.002.2022 & FSSAI.FR.16.003.2022 for analysis of iron, folic Acid and Vitamin B12 respectively.

(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 Kernals	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.*	Uric Acid, mg/Kg, on mass basis, not more than	100.0			
9.*	Yeast and Mould Count (cfu/g)	1×10^2		-	
10.*	Aerobic Plate Count (cfu/g)	1×10^4		-	
11.	Length (in mm)	-			
12.	Breadth (in mm)	-			
13.	Thousand kernel weight	-			
14.	True density	-			
15.	Prepared from (Raw/Parboiled) Rice	-			

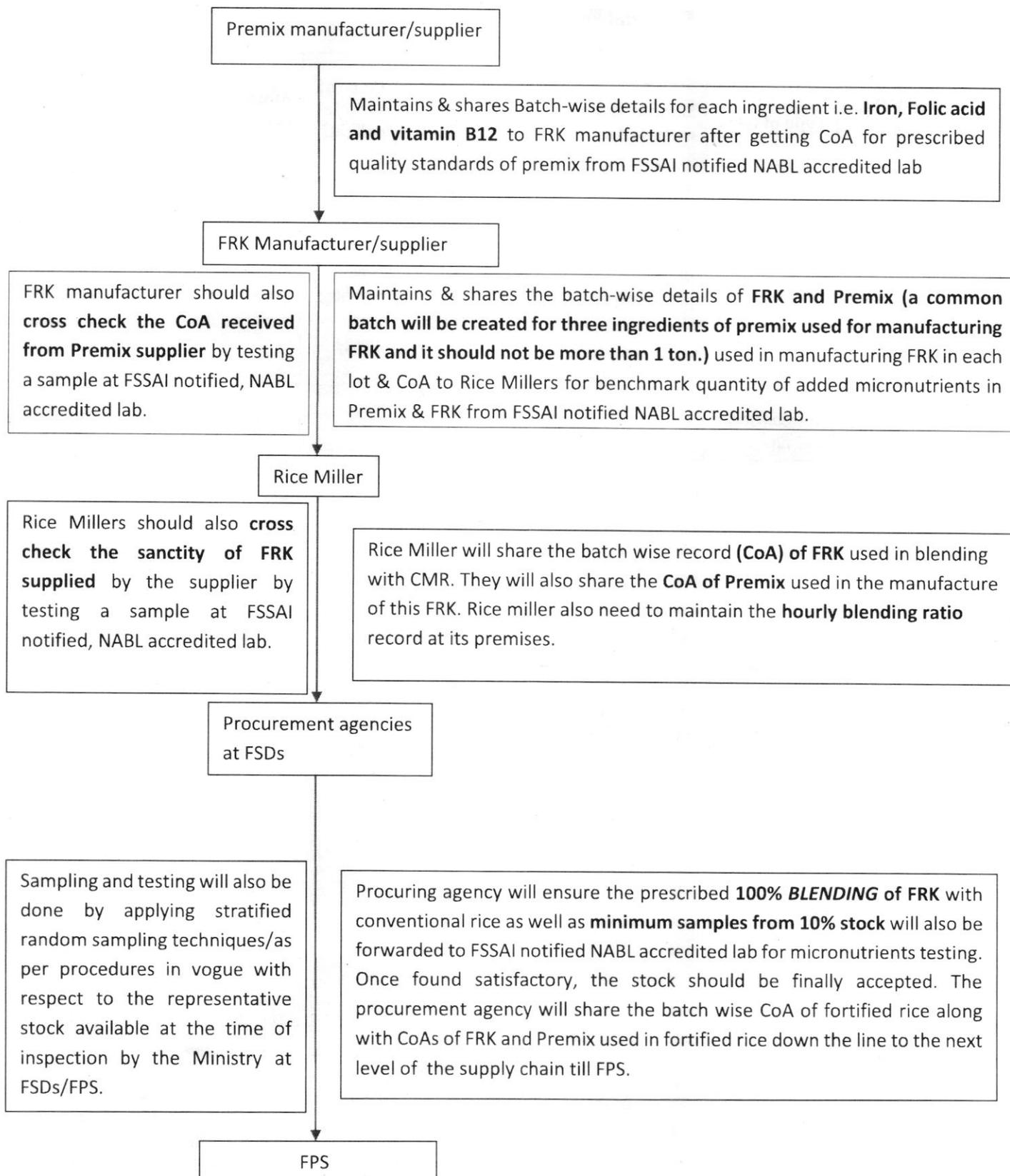
*) The reference range is as per the limits mentioned by FSSAI

For parameters 11-14 the FRK should match the parameter of raw rice to which FRK is to be blended

Remarks: Best before _____

(Authorized Signature)

Annexure: Flow chart for sampling and testing upto FSD/FPS Level



Quality control matrix of premix, FRKs and Fortified rice.

	Timing of testing	Type of tests	Sample to be collected by	Place of testing	Place of sample collection	Approved by and action taken on approval	Action (If not approved and/or test/s is failed)
Supply of premix	Before dispatch of Premix	<ul style="list-style-type: none"> ○ Physico-chemical requirements ○ Micronutrient composition 	Premix manufacturer	FSSAI- notified NABL- accredited lab	Premix manufacturer facility	FRK manufacturer Action: A batch of premix is shipped to the FRK manufacturer	Action: Rejection of a batch of premix and production of a new batch of premix by the premix manufacturer
Supply of FRK	Before dispatch of FRK	<ul style="list-style-type: none"> ○ Physical attributes ○ Micronutrients testing ○ Microbiological testing 	FRK manufacturer	Physical attributes (the internal quality lab of FRK manufacturer or FSSAI-notified NABL- accredited lab) Micronutrients testing (FSSAI-notified NABL- accredited lab) Microbiological testing (FSSAI-notified NABL- accredited lab)	FRK manufacturer facility	Rice miller (in case the rice miller is procuring the FRKs) Procurement agency in case the state is procuring the FRKs centrally. Action: A batch of FRKs is shipped to the rice mill or the procurement agency.	Action: Rejection of a batch of FRKs and production of a new batch of FRKs by the FRK manufacturer
	At the time of receipt of FRKs	<ul style="list-style-type: none"> ○ Micronutrient testing 	Rice Miller/ Procurement agency	FSSAI- notified NABL- accredited lab	Rice mill/place of storage	Rice Miller/ Procurement agency Action: Continued use of a received batch of FRKs for blending with conventional rice	Action: Rejection of the batch of FRKs and production of a new batch of FRKs by the FRK manufacturer

	Timing of Testing	Tests	Samples to be collected by	Place of testing	Place of sample collection	Approved by and action taken by	Action (If not approved and/ or test/s is failed)
Production of the Fortified rice	During the Blending of FRK with CMR	Blending ratio through BET(hourly basis)	Rice miller	Internal quality lab/ facility of the rice miller	Rice miller facility	Internal checks/ approval by the rice miller State Food and Civil Supplies Department may do random checks of the records Action: Continued production of fortified rice	Action: Necessary corrective action to be taken by the rice miller at the blending equipment to achieve the ratio of 1:100. <i>Rejection of a batch of fortified rice and production of a new batch of fortified rice by the rice miller</i>
Supply of the fortified rice	At the time of receipt at the storage point	Physical attributes/ refractions including blending ratio Weight	Procuring agency (FCI/ state agencies, as the case may be)	Internal quality lab	FCI /state storage point	Verification of CoA of premix and FRKs by the FCI or the State procurement agency (as applicable) Action: Acceptance of the lot/ batch of fortified rice	Action: Rejection of a lot of fortified rice and production of a new lot of fortified rice by the rice miller and

		Stenciling prescriptions					other penal provisions under consultation with the ministry
	After receipt, before dispatch to the next point in supply chain	Micronutrient testing	Procuring agency (FCI/ state agencies, as the case may be)	FSSAI-notified NABL-accredited lab	FCI /state storage point	Action: Continued storage of fortified rice at the FCI godown/state godown.	Action: Rejection of a lot of fortified rice and production of a new lot of fortified rice by the rice miller and other penal provisions under consultation with the ministry

Quality control of the fortified rice under domestic supply chain

	Timing of testing	Type of tests	Sample to be collected by	Place of testing	Place of sample collection	Approved by and action taken on approval	Action (If not approved and/or test/s is failed)
Monitoring of quality control in FRKs at the FRK manufacturer	Monthly basis	Microbiological & Micronutrient testing Quality inspections	Food Safety officer / State Food and Civil Supplies Department	Microbiological /Micronutrient testing (FSSAI-approved NABL-accredited lab)	FRK manufacturing unit	Action: Continued production of FRKs by the FRK manufacturer	Action: As per the existing guidelines/provisions

Monitoring of quality control in fortified rice at the FPS	/Monthly basis	Micronutrient testing & microbiological Quality inspections including verifying records of blending ratio, CoAs of FRK, and premix.	Food Safety officer / State Food and Civil Supplies Department	Micronutrient & microbiological testing (FSSAI-notifies NABL-accredited lab)	FPS	Action: Continue distribution.	Action: As per the existing guidelines/ provisions
Monitoring of quality standards of FR and FRK at FRK manufacturer/ rice mill/FSD/FPS /Rail heads/truck heads/Procurement centers/other transit points	Periodic and surprise check	Quality inspections	Department of Food & Public Distribution	Testing at departmental labs/FSSAI-notified, NABL-accredited lab	FRK manufacturer/ rice mill/FSD/FPS /Rail heads/truck heads/Procurement centers/other transit points	Action: Continued production of fortified rice by the rice miller/storage/distribution as applicable	As per the guidelines issued by letter dated 16-07-2021 for Monitoring the quality of Food Grain Stocks procured under DCP. The same will be followed for centralized procurement

Sampling for Quality control of Fortified rice by the Department of Food & Public Distribution – Draw a minimum sample from stocks available at the time of inspection;

- 100% of the stock up to 1000 MT
- 10% of the stock up to 10,000 MT
- 5% of the stock for more than 10,000MT

Sampling for Quality control of the FRK by the Department of Food & Public Distribution – Draw a minimum sample from stocks available at the time of inspection;

- 1 sample from every 1-ton batch of FRK stock (Draw randomly from minimum 1 and maximum 10 bags).

The procuring agencies (FCI/State agencies) may follow their existing sampling and testing protocols regarding sample collection.