



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR

No. 2021- _____

SUBJECT : Revised Bureau Circular No. 2007-010 entitled Guidelines in the Initial Issuance and Renewal of License To Operate for Iron-Rice Premix Manufacturer/Repacker/Importer and Updating of the Standards for Iron Rice Premix

I. BACKGROUND

Pursuant to Republic Act No. 8976 entitled *An Act Establishing the Philippine Food Fortification Program and for other Purposes*, particularly iron fortification of rice to achieve its goal of addressing Iron Deficiency Anemia (IDA), the subject Bureau Circular No. 2007-010 needs to be revised to ensure the iron content in *iron-rice premix* is at the suitable level to help curb IDA in the country.

Rice fortification includes the addition of highly concentrated iron-rice premix to raw rice at required mixing ratio to enable the iron-fortified rice to be within the standard. During the enactment of the law in 2000, the technology available for the production of iron rice premix was coating rice with iron to produce iron rice premix. This technology was used as basis or the standard of iron fortified rice as well as in the BFAD Circular No. 2007-010 subject of this revision. While the use of coating technology for the preparation of iron-rice premix has improved over time to reduce iron losses during the usual washing prior to cooking and to produce kernels that meet nutrient retention requirements under different conditions and preparation methods, an evolving technology such as extrusion is an additional option for iron-rice premix fortification. The Food and Nutrition Research Institute (FNRI) of the Department of Science and Technology has developed an extrusion technology for the production of iron-rice premix. The iron-rice premix produced by extrusion has minimal loss of iron during washing of rice prior to cooking. Studies of FNRI also showed that iron-rice premix produced by extrusion is efficacious.

Establishing a common standard of iron content of iron fortified rice using either the coating of extruding technology for iron fortified premix is unlikely, thus a computed iron level or raw and cooked fortified rice using extruded and coated iron-rice premix per blending ratio as a standard level of iron in the iron-rice premix is established.



Based on the foregoing, the revision of Bureau Circular No. 2007-010 is hereby imperative.

II. OBJECTIVES

This Circular aims to provide updated guidelines and standards on the suitable level of iron in rice in the manufacture of iron-rice premix to help address iron deficiency anemia in the country.

III. SCOPE

This Circular shall cover person(s) or establishment(s) that manufacture, repack, import iron rice premix used as an ingredient for iron fortification of rice as provided in Republic Act 8976.

Further, this Circular shall be applicable as guidance to all Food and Drug Regulatory Officers under the Regional Field Offices in conducting evaluation and inspection of iron-rice premix manufacturer/repacker/importer for the initial issuance and renewal of License to Operate.

IV. GUIDELINES

The procedures for Licensing and Inspection of iron-rice premix manufacturer/repacker/importer shall be consistent and in accordance with AO 2014-0029, AO 2020-0017 and/or current rules and regulations containing the specific procedures of FDA.

V. PENALTY CLAUSE

Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under RA 8976 otherwise known as the "Philippine Food Fortification Act of 2000", and its Implementing Rules and Regulations.

VI. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions of this Circular shall not be affected.

VII. REPEALING CLAUSE

Bureau Circular No. 2007-010 and other issuances inconsistent with this Circular are hereby repealed.

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the Office of the National Administrative Register.

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Director General

UPDATED STANDARDS FOR IRON-RICE PREMIX

I. SCOPE

This standard applies to all manufacturers, distributors and importers of iron-rice premixes whose produce shall be distributed in the domestic market.

II. DESCRIPTION OF THE PRODUCT

Iron-Rice Premix should be made from rice and food grade ferrous sulphate or any FDA Approved iron fortificant and food grade binders and additives sufficient to ensure quality, efficacy, and shelf life stability at ambient conditions and shall be packed in any suitable packaging material that could prevent the entry of moisture and contaminants.

III. DEFINITION OF TERMS

For the purpose of this standard, the following terms shall mean:

1. **Current Good Manufacturing Practices (cGMP)** – a quality assurance systems aimed at ensuring the products are consistently manufactured. Packed or repacked or held to a quality appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedures.
2. **Food Additives** – any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use) if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through procedures to be safe under the conditions of the intended use
3. **Food Standard** – regulatory guideline that defines the identity of a given food product (i.e. its name and the ingredients used for its preparation) and specifies the minimum quality factors and when necessary, the required fill of the container. It may also include specific labeling requirements generally applicable to all prepackaged foods.'

4. **Fortification** – shall mean the addition of nutrients to processed foods at levels above the natural state.
5. **Ingredient** – any substance including food additive, used as a component in the manufacture, preparation of a food and present in the final products in its original or modified form.
6. **Labeling** – any written, printed or graphic matter (1) upon any articles or any of its container or wrappers and/or (2) accompanying the packaged food.
7. **Lot** – food produced during a period of time and under more or less the same manufacturing condition indicated by a specific code.
8. **Moisture Content** – the percentage weight of water in relation to the dry weight of the product.
9. **Packaging** – the process of packing that is part of the production cycle applied to a bulk product to obtain the finished product. Any material, including painted material, employed in the packaging of a product including any outer packaging used for transportation of shipment.
10. **PDRI- shall refer to Philippine Dietary Reference Intakes**

IV. COMPOSITIONS AND QUALITY FACTORS

1. General Requirements

Iron-rice premix shall have the following characteristics

a. Iron Content

The product shall contain a minimum of 300 mg iron/ 100 grams and a maximum of 2,400 mg iron/ 100 grams provided that the mixing ratio of not less than 1:100 up to not more than 1L400 is indicated in the label resulting in an iron content of 2-6 mg iron per 100 mg of raw (uncooked) iron fortified rice and a minimum of 0.6 mg iron per 100 grams of cooked iron fortified rice.

b. Moisture Content

The product shall have a moisture content of a maximum of 13% based on the dry weight of the product.

V. FOOD ADDITIVES

Food additives when used shall be in accordance with the current regulations established by the Food and Drug Administration (BC 2006-016: Updated List of Food Additives) and/or Codex Alimentarius Commission or their latest revisions.

VI. HYGIENE

1. It is recommended that the Iron Rice Premix covered by the provision of this standard be prepared and handled in accordance with the appropriate sections of the FDA A.O. No. 153 s. 2004 – Guidelines Current Good Manufacturing Practices in Manufacturing, Packing, Repacking or Holding Food and Processed and recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1- 1969 Rev. 4- 2003) or latest revisions.
2. When tested by appropriate methods of sampling and examination, the iron rice premix:
 - Shall be free from filth that may pose a hazard to health
 - Shall not contain any substance originating from microorganisms in amounts which may represent a hazard to health
 - Shall be free from microorganisms capable of development under normal conditions of storage

VII. PACKAGING

The packaging material should provide adequate product protection against the entry of moisture and adequate strength to withstand normal handling damage.

VIII. LABELING

1. Each container shall be handled and marked with the following information or in accordance with FDA's Labeling Regulation:
 - a. The name of the product as "Iron Coated Rice Premix" or "Iron Extruded Rice Premix" should be indicated on the package.
 - b. The brand name
 - c. The name and address of the manufacturer, packer and distributor
 - d. Open date marking

The words “Best”/ “Consume Before”/ “Use by Date” indicating the end of period at which the product shall retain its optimum quality attributes at defined storage conditions.

- e. Lot identification code
 - f. The words “Product of the Philippines” or the country or origin if imported
 - g. The type of iron used
 - h. Instruction for use including mixing ratio
 - i. This product is not suitable for direct human consumption should be indicated in big and bold letters
 - j. Net weight contains a maximum 25 kg
2. The ink of the label graphics should not smear or wear off upon contact with any liquid and/or hard surface.

IX. METHODS OF ANALYSIS AND SAMPLING

1. Determination of Iron Content
According to the Official Method of Analysis of AOAC International (2005) 28th Edition, Official Method 975.03 for iron in grains.
2. Determination of Moisture Content
According to the AOAC Official Method of Analysis, 16th Edition, 1995 Method No. 934.38 B.
3. Method of Sampling
Sampling plan shall be in accordance with the FAO/WHO Codex Alimentarius Sampling Plan for Prepackaged Foods – CAC/RM 42-1969, Codex Alimentarius 13, 1994.

Fortificant	Minimum Acceptable Level	Maximum Tolerable Level
Iron Ferrous Sulfate	60 mg Fe/ kg raw rice	90 mg Fe/ kg raw rice

Computed Iron Level of Raw and Cooked Fortified Rice Using Extruded and Coated Iron Rice Premix per Blending Ratio

remix fixing ratio	Computed Iron level of Iron Rice Premix (IRP), mg iron/100g based on revised FDA standard (300-2400 mg iron/100g)																					
	300	400	500	600	700	800	900	1000	1100	1200	1300	1400	1500	1600	1700	1800	1900	2000	2100	2200	2300	2400
raw IFR	Computed iron level of raw iron fortified rice (IFR) based on revised FDA standard (2-6 mg/100g)																					
:100	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00	16.00	17.00	18.00	19.00	20.00	21.00	22.00	23.00	24.00
:200	1.50	2.00	2.50	3.00	3.50	4.00	4.50	5.00	5.50	6.00	6.50	7.00	7.50	8.00	8.50	9.00	9.50	10.00	10.50	11.00	11.50	12.00
:300	1.00	1.33	1.67	2.00	2.33	2.67	3.00	3.33	3.67	4.00	4.33	4.67	5.00	5.33	5.67	6.00	6.33	6.67	7.00	7.33	7.67	8.00
:400	0.75	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00	5.25	5.50	5.75	6.00
cooked extruded R-FP	Computed iron level of cooked IFR used on the retention data of extruded micronized dispersible Ferric Pyrophosphate (FNRI-DOST and ILSI Project) (minimum of 0.6 mg/100g)																					
:100	1.25	1.66	2.08	2.49	2.91	3.32	3.74	4.15	4.57	4.98	5.40	5.81	6.23	6.64	7.06	7.47	7.89	8.30	8.72			10
:200	0.63	0.83	1.04	1.25	1.45	1.66	1.87	2.08	2.28	2.49	2.70	2.91	3.11	3.32	3.53	3.74	3.94	4.15	4.36			5
:300	0.42	0.55	0.69	0.83	0.97	1.10	1.25	1.38	1.52	1.66	1.80	1.90	2.08	2.21	2.35	2.49	2.63	2.76	2.91			3.3
:400	0.31	0.42	0.52	0.62	0.73	0.83	0.93	1.04	1.14	1.25	1.35	1.45	1.56	1.66	1.76	1.87	1.97	2.08	2.18			2.5
cooked extruded R-FS	Computed iron level of cooked iron fortified rice (IFR) based on the retention data of extruded Ferrous Sulfate (FNRI-DOST and ILSI Project) mg iron/100g																					
:100	1.17	1.56	1.95	2.33	2.72	3.11	3.50	3.89	4.28	4.67	5.06	5.45	5.84	6.22	6.67	7.00	7.39	7.78	8.17			9.4
:200	0.59	0.78	0.97	1.17	1.36	1.56	1.75	1.95	2.14	2.33	2.53	2.72	2.92	3.11	3.31	3.50	3.70	3.89	4.08			4.7
:300	0.39	0.52	0.65	0.78	0.91	1.03	1.17	1.30	1.42	1.56	1.68	1.88	1.95	2.07	2.20	2.33	2.46	2.59	2.72			3.1
:400	0.29	0.39	0.49	0.58	0.68	0.78	0.88	0.97	1.07	1.17	1.26	1.36	1.46	1.56	1.65	1.75	1.85	1.95	2.04			2.3
cooked extruded R-FS	Computed iron level of cooked iron fortified rice (IFR) based on the retention data using coated ferrous sulfate (FNRI-DOST and ILSI Project), mg iron/100g																					
:100	0.97	1.29	1.61	1.93	2.25	2.58	2.90	3.22	3.54	3.86	4.19	4.51	4.83	5.15	5.47	5.80	6.12	6.44	6.76			7.7
:200	0.48	0.64	0.81	0.97	1.13	1.29	1.45	1.61	1.77	1.93	2.09	2.25	2.42	2.25	2.74	2.90	3.06	3.22	3.38			3.9
:300	0.32	0.43	0.54	0.64	0.75	0.86	0.97	1.07	1.18	1.29	1.39	1.59	1.61	1.72	1.82	1.93	2.04	2.14	2.25			2.9
:400	0.24	0.32	0.40	0.48	0.56	0.64	0.72	0.81	0.89	0.97	1.05	1.13	1.21	1.29	1.37	1.45	1.53	1.61	1.69			1.9