



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR
No. 2007-010-A

22 DEC 2021

SUBJECT : Updated Standards for Iron-Rice Premix Amending 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 Setting Forth the Standards for Iron Rice Premix"

I. BACKGROUND

Pursuant to Republic Act (RA) 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 entitled "*Guidelines in the Initial Issuance and Renewal of License To Operate for Iron Rice Premix Manufacturer/Repacker/Importer and Setting Forth the Standards for Iron Rice Premix*" 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 the premix. This technology was used as the basis for 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 or extruding technology for iron fortified premix is unlikely, thus a computed

iron level of 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 amendment of Bureau Circular No. 2007-010 is hereby imperative.

II. OBJECTIVES

This Circular aims to provide guidelines on updated standards in the manufacture, repack, and/or import 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 and/or import iron-rice premix used as an ingredient for iron fortification of rice as provided in RA No. 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. DEFINITION OF TERMS

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

- A. Food Additives** – refers to any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.

- B. 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.
- C. Fortificant** – a substance, in chemical or natural form, added to food to increase its nutrient value.
- D. Fortification** – the addition of nutrients to processed foods or food products at levels above the natural state. As an approach to control micronutrient deficiency, food fortification is addition of a micronutrient, deficient in the diet, to a food which is widely consumed by specific at-risk groups.
- E. Good Manufacturing Practices (GMP)** – a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to a quality appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedures.
- F. Ingredient** – means any substance, including a food additive, used as a component in the manufacture or preparation of food and present in the final product (in its original or modified form).
- G. Kernel Shavings** – very thin kernels or randomly sized or shaped clumps of dried extruded iron-rice premix.
- H. Labeling** – means any written, printed or graphic matter (1) upon any article or any of its container or wrappers or (2) accompanying the packaged food.
- I. Lot/Batch** – refers to quantity of food produced under essentially the same conditions during a particular production schedule.
- J. Lumped Kernels** – a kernel, thin kernel, and/or shaving that merged to form a large lump; some may look like enlarged whole kernels.
- K. Moisture Content** – the percentage weight of water in relation to the dry weight of the product.
- L. Packaging** – refers to an activity where a product is contained AND SEALED with the intention of storage and/or transport.

M. Thin Kernel – kernel with only half the size of a whole kernel or is crescent-shaped.

N. Whole Kernel – kernel with shape and size similar to well-milled rice; most prominent shape or size throughout the iron-rice premix.

V. GUIDELINES

A. The procedures and requirements for Licensing and Inspection of iron-rice premix manufacturer/repacker/importer shall be consistent and in accordance with the following:

1. Updated standards for iron-rice premix stipulated in the Annex A; and
2. Computed iron level of raw and cooked fortified rice using extruded and coated iron-rice premix per blending ratio in Annex B of this issuance;
3. Administrative Order (AO) No. 2014-0029 entitled *Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and For Other Purposes*;
4. AO No. 2020-0017 entitled *Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003*; and
5. AO No. 153 s. 2004 entitled *Revised Guidelines on Current Good Manufacturing Practice in Manufacturing, Packing, Repacking, or Holding Food* or latest amendments and pertinent rules and regulations containing the specific procedures of FDA.

B. Food establishments and other concerned personnel covered by the Scope of this Circular shall remain knowledgeable and updated in every provision of the said AOs and above-mentioned requirements and other pertinent rules and regulations.

VI. PENALTY CLAUSE

Any establishment found to be in violation of any provision of this issuance shall be a ground for disapproval of application and suspension or cancellation of License or Authorization pursuant to Section 4, Article 1, Book II of the Implementing Rules and Regulation (IRR) of RA No. 9711.

Notwithstanding the preceding paragraph, nothing in this section shall restrict the FDA in imposing the penalty and sanctions as prescribed under RA No. 8976 otherwise known as "Philippine Food Fortification Act of 2000" and its IRR.

VII. SEPARABILITY CLAUSE

If any provision of 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.

VIII. REPEALING CLAUSE

Provisions of previous issuances such as Bureau Circular (BC) No. 2007-010 which are contrary to those reflected hereon are modified/amended and/or repealed accordingly.

IX. EFFECTIVITY

This Circular shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20211006083010

UPDATED STANDARDS FOR IRON-RICE PREMIX

I. SCOPE

This standard applies to iron-rice premix for domestic market distribution intended for human consumption.

II. DESCRIPTION OF THE PRODUCT

Iron-Rice Premix shall be made from rice and food grade ferrous sulphate, or (micronized) ferric pyrophosphate or any FDA Approved iron fortificant stipulated in the AO No. 4-A s. 1995 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. COMPOSITION AND QUALITY FACTORS

A. General Requirements

Iron-rice premix shall have the following characteristics:

1. Iron Content

The product shall contain a minimum of 300 mg iron (Fe)/100 grams (g) and a maximum of 2,400 mg Fe/100 g provided that the mixing ratio of not less than 1:100 up to not more than 1:400 is indicated in the label resulting in an iron content of 2 to 6 mg Fe/100 g of raw (uncooked) iron fortified rice and 0.6 to 2.2 mg Fe/100g of cooked iron fortified rice. For further information on how to arrive at values: see Annex B for reference in terms of proportion and the availability of iron in raw and uncooked iron fortified rice also considering the losses during washing.

2. Moisture Content

The product shall have a maximum moisture content of 13%.

3. Color

The iron-rice premix shall have light yellow to yellow color based on the prevailing scientific reference.

4. The iron rice kernels shall be composed of at least 85% whole kernels and not more than 15% off-shaped kernels, namely: lumped, thin-shaped, and/or shavings.

5. No rancid-like odors.

6. Free from insects, filth and other extraneous matter.

IV. FOOD ADDITIVES

Food additives when used shall be in accordance with the current regulations established by the Food and Drug Administration i.e. BC 2006-016: Updated List of Food Additives or latest revision, updated CODEX STAN 192-1995 on General Standards for Food Additives or latest revision.

V. HYGIENE

A. It is recommended that the Iron-Rice Premix covered by the provision of this standard shall be prepared and handled in accordance with the appropriate sections of the DOH A.O. No. 153 s. 2004 entitled "*Revised Guidelines on Current Good Manufacturing Practice in Manufacturing, Packing, Repacking, or Holding Food*" and recommended International Code of Practice – General Principles of Food Hygiene (CXC 1-1969, Revised 2020) or latest revisions.

B. When tested by appropriate methods of sampling and examination, the iron-rice premix shall conform with the specific safety criteria in Table 1 and Table 2.

Table 1. Limit for Microorganisms and Contaminant in Iron-Rice Premix

Test Parameters	n	c	m	M
Molds and Yeast count, cfu/g	5	2	10 ³	10 ⁴
Aflatoxin, Total (ppb)	10			
Reference: (MR26) USDA Commodity Requirements Milled Rice and Fortified Milled Rice for Use in International Food Assistance Programs Effective Date: 13 July 2018				

Table 2. Maximum Level for Arsenic, Cadmium, and Lead in Iron-Rice Premix

Test Parameters	Maximum Level (ML) mg/kg
Arsenic	0.2
Cadmium	0.4
Lead	0.2
Reference: (PNS/BAFS 194:2017) General Standard for Contaminants and Toxins in Food and Feed	

VI. PACKAGING

The packaging material shall provide adequate product protection against the entry of moisture and adequate strength to withstand normal handling condition e.g., opaque polyethylene or polypropylene plastic and aluminum stand up pouches.

VII. STORAGE CONDITION

The product shall be stored in a cool dry place under 30 to 34 degrees Celsius with relative humidity not greater than 85%, away from ultraviolet light. The premises, warehousing, and distribution should be in accordance with AO No. 153 s. 2004 or its latest version.

VIII. LABELING

A. Each container shall be handled and marked with the following information or in accordance with A.O. No. 2014-0030 entitled “*Revised Rules and Regulation Governing the Labelling of Prepackaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984*” or its latest amendments:

1. The name of the product shall be “Iron Coated Rice Premix” or “Iron Extruded Rice Premix” in accordance with the method of fortification used and shall be prominently and legibly indicated on the label of Iron-Rice Premix.
2. The brand name and/or trademark.

If the establishment has a registered brand name or trademark, it shall be mandatory to declare the brand name or trade mark. May not be declared on the label if the product will be used for further processing.

3. The complete name and address of the manufacturer, packer and distributor.
4. Open date marking.

The words “Expiry” or Expiry Date”/ “Use-by-date”/ “Consume Before Date (Recommended last consumption date)” indicating the end of period at which the product shall retain its optimum quality attributes at defined storage conditions.

Expiration/expiry date shall be printed clearly, conspicuously and legibly on all product labels in the following order: Day, Month, Year. The declaration of day and year are numerical while the declaration of month must be in words to avoid confusion (e.g., Expiry date: 01 January 2012 or 01Jan12).

5. Lot/Batch identification code.
6. The words “Product of the Philippines” or the country of origin, if imported.
7. Complete list of ingredients specifying the type of iron fortificant used.
8. Instruction for use including mixing ratio.

9. The statement "This product is not suitable for direct human consumption" shall be indicated on the label conspicuously in big and BOLD letters.

10. Net weight shall be in International System of Units (SI Units).

11. Storage instructions.

12. Specific iron content.

B. The ink of the label graphics shall not smear or wear off upon contact with any liquid and/or hard surface.

IX. METHODS OF ANALYSIS AND SAMPLING

A. Determination of Iron Content

According to the AOAC Official Method of Analysis (2019) 21st Edition, AOAC 975.03; AOAC Official Method of Analysis (2019) 21st Edition, AOAC 944.02.

B. Determination of Moisture Content

According to AOAC Official Method of Analysis (2019), 21st Edition, AOAC 945.38B; AOAC Official Method of Analysis (2019) 21st Edition, AOAC 925.10.

C. Determination of Aflatoxin

ELISA Method or Liquid Chromatography Method.

D. Determination of Heavy Metals

Atomic Absorption Spectrophotometric Method.

E. Method of Sampling

Sampling plan shall be in accordance with the Codex General Guidelines on Sampling CAC/GL 50-2004.

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

Premix Mixing ratio	Computed Iron level of Iron Rice Premix (IRP), mg Iron/100g based on revised FDA standard (300-2400 mg/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)																					
1:100	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
1:200	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
1:300	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
1:400	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 IFR-FP	Computed iron level of cooked IFR based on the retention data of extruded micronized dispersible Ferric Pyrophosphate (FNRI-DOST and ILSI Project) (minimum of 0.6 mg/100g)																					
1:100	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
1:200	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
1:300	0.42	0.55	0.69	0.83	0.97	1.10	1.25	1.38	1.52	1.66	1.80	1.80	2.08	2.21	2.35	2.49	2.63	2.76	2.91			3.3
1:400	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 IFR-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																					
1:100	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
1:200	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
1:300	0.39	0.52	0.65	0.78	0.91	1.03	1.17	1.30	1.42	1.56	1.68	1.68	1.95	2.07	2.20	2.33	2.46	2.59	2.72			3.1
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 Coated IFR-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																					
1:100	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
1:200	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
1:300	0.32	0.43	0.54	0.64	0.75	0.86	0.97	1.07	1.18	1.29	1.39	1.39	1.61	1.72	1.82	1.93	2.04	2.14	2.25			2.9
1:400	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
For details, refer to Annex A, Section III. 1. a. Iron Content																						