



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS

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BUREAU CIRCULAR
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SUBJECT : 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. RATIONALE / BACKGROUND

Republic Act 8976 mandates the fortification of raw rice with iron to produce iron fortified rice as part of the Philippine Food Fortification Program for the elimination of iron deficiency anemia.

Iron fortification of raw rice requires the addition and mixing of an iron rice premix, usually produced from rice either coated or extruded with highly concentrated iron. The addition of iron rice premix to raw rice is dependent on the iron content of the iron rice premix.

These guidelines will be used by BFAD, at the National and the Centers for Health Development (CHD's), for the issuance and renewal of a BFAD license to operate for the production, repacking and importation of iron rice premix to ensure that the premix conforms with the quality standards of BFAD to ensure that the iron rice premix is fit for human consumption and would supply the necessary iron to contribute to anemia reduction as provided for by RA 8976.

II. SCOPE

This Order 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 Order shall be applicable as guidance/directive to all Food and Drug Regulatory Officers under the CHD's in conducting evaluation and inspection of iron rice premix manufacturer/repacker/importer for the issuance and renewal of License to Operate.

III. DIRECTIVE

In view of the foregoing considerations, this Bureau issues the following directives:

1. The procedures for Licensing and Inspection of iron rice premix manufacturer/repacker/importer shall be consistent and in accordance with current and existing rules and regulations and specific procedures of BFAD. Such procedures shall include existing reporting and approval system and relationship between the CHD and the BFAD.
2. The standards for iron rice premix are hereto attached as Annex A.

IV. REPEALING CLAUSE

Provisions of previous issuances which are contrary to those reflected hereon are modified, and /or repealed accordingly.

V. SEPARABILITY

If any provision of this Order is declared as unconstitutional, or not valid, the rest of the provisions hereon shall still subsist given their effect in entirety.

VI. EFFECTIVITY

This Order shall be effective within fifteen (15) days after publication.


PROF. LETICIA BARBARA B. GUTIERREZ, MS
Director IV

STANDARDS FOR IRON RICE PRE-MIX

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. Definition of terms

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

1. Current Good Manufacturing Practices (cGMP) – a quality assurance system 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 other than or in addition to the 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. **RDA** – means Recommended Dietary Requirements

III. Description of the Product

Iron Rice Premix shall have an iron from food grade ferrous sulfate sufficient to ensure quality and shelf life stability at ambient conditions and shall be packed in any suitable packaging materials.

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 600 mg/iron grams and a maximum of 2,400 mg/100 grams provided that the mixing ratio is indicated not more than 1:400 in the label to contain 6-9 mg. iron per 100 grams of raw (uncooked) fortified rice and 1-2 mg. iron per 100 grams of cooked rice.

The final basis for passing the standard for iron content is the iron content in the cooked rice.

b. Moisture Content

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

IV. Food Additives

Food additives when used shall be in accordance with the current regulations established by the Bureau of Food and Drugs (BC 2006-016-Updated List of Food Additives) and/or Codex Alimentarius Commission

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 BFAD 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)

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 in accordance with BFAD's Labeling Regulation:

- a. The name of the product as "Iron Rice Premix" or Extruded Iron Rice Premix
- 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 ration
- 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. Method of Analysis and Sampling

1. Determination of Iron Content

2. Determination of Moisture Content

According to the AOAC Official Method of Analysis, 16th edition, 1995, Method No. 934.06

3. Method of Sampling

Sampling shall be in accordance with the FAO/Who Codex Alimentarius Sampling Plans for Prepackaged Foods – CAC/RM 42-1969, Codex Alimentarius 13, 1994, Mandatory Food Fortification per RA 8976 – Rule VI (IRR), all rice except brown rice and locally produced glutinous rice, to be fortified with iron:

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