

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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**THE IMPLEMENTING RULES AND REGULATIONS
OF REPUBLIC ACT NO. 8976**

ENTITLED:

**“AN ACT ESTABLISHING THE PHILIPPINE FOOD FORTIFICATION PROGRAM
AND FOR OTHER PURPOSES”**

Pursuant to Section 12 of Republic Act No. 8976, the following Implementing Rules and Regulations are hereby formulated for the effective implementation of the said Republic Act by authorized officials and representatives of the Department of Health (DOH), in consultation with other concerned government agencies, non-government organizations, private sector and consumer groups.

RULE I - TITLE

SECTION 1. This document shall be known as the “IMPLEMENTING RULES AND REGULATIONS FOR THE PHILIPPINE FOOD FORTIFICATION ACT OF 2000” established by Republic Act No. 8976.

RULE II - DECLARATION OF POLICIES

SECTION 1. In the implementation of provisions of Rep. Act No. 8976, the government shall be guided always by the provisions of Sec. 2 thereof, which provides as follows:

SECTION 2. Declaration of Policies – Section 15 of Article II of the Constitution provides that the State shall protect and promote the right to health of the people and instill health of the people and instill health consciousness among them.

The State recognizes that nutritional deficiency problems in the Philippines, based on nutrition surveys, include deficiency in energy, iron, vitamin A, iodine, thiamin and riboflavin. To a minor extent, the Filipino diet is also deficient in ascorbic acid, calcium and folate.

The State recognizes that food fortification is vital where there is a demonstrated need to increase the intake of an essential nutrient by one or more population groups, as manifested in dietary, biochemical or clinical evidences of deficiency. Food Fortification is considered important in the promotion of optimal health and to compensate for the loss of nutrients due to processing and/or storage of food.

Food fortification, therefore, shall be carried out to compensate for the inadequacies in Filipino diet, based on present needs as measured using the most recent Recommended Dietary Allowance (RDA).

RULE III - DEFINITION OF TERMS

SECTION 1. For the purpose of this Act, the following terms shall mean:

- (a) Acceptable standards on food fortification – requirements for fortification set by the DOH through BFAD in consultation with other concerned agencies and industry representative groups.
- (b) BFAD – the Bureau of Food and Drugs of the Department of Health
- (c) Brown rice – palay form which the hull has been removed. This is also known as “dehulled rice” or “husked rice.”
- (d) Cooking oil – edible oil derived from vegetable sources intended for human consumption, including its use in food preparation or in processing other food products.
- (e) DOH – stands for Department of Health (the lead agency in the implementation and monitoring of the said Act).
- (f) Food service establishment – refers to hotels, restaurants, carinderias, catering firms, hospitals and other related outlets, which serve or sell food to customers.
- (g) 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 the addition of a micronutrient, deficient in the diet, to a food, which is widely consumed by specific at-risk groups.
- (h) Fortificant – a substance, in chemical or natural form, added to food to increase its nutrient value.
- (i) Glutinous rice – a special type of rice whose grains are white and opaque in appearance. It coagulates into a sticky mass when cooked.
- (j) Importer – any person, natural or juridical, that brings in food/food products from other countries for its own use or for wholesale/retail distribution to other food establishments or outlets. An importer may also be a manufacturer.
- (k) Manufacturers – the refinery in case of refined sugar or cooking oil, the miller in case of flour, or rice, or the importer in case of imported processed foods or food products, or the processor in case of other processed food or food products.
- (l) Maximum tolerable level – the reference point to check for the safety and quality of the product using individual samples.
- (m) Micronutrient – an essential nutrient required by the body in very small quantities; recommended intakes are in milligrams or micrograms.
- (n) Minimum acceptable level – the level of fortificant required by BFAD that should appear in the label and which should also be present at the retail level.
- (o) NNC – the Governing Board of the National Nutrition Council

- (p) Nutrient - Any chemical substance needed by the body for one or more of these functions: to provide heat or energy, to build and repair tissues, and to regulate life processes. Although nutrients are found chiefly in foods, some can be synthesized in the laboratory like vitamin and mineral supplements or in the body through biosynthesis.
- (q) Nutrition facts - a statement or information on food labels indicating the nutrient(s) and the quality of said nutrient found or added in the processed foods or food products.
- (r) Nutrition labeling - a system of describing processed foods or food products on the basis of their selected nutrient content. It aims to provide accurate nutrition information about each food. This is printed in the food labels as "Nutrition Facts."
- (s) Processed food or food products - food that has been subjected to some degree of processing like milling, drying, concentrating, canning, or addition of some ingredients which changes partially or completely the physio-chemical and/or sensory characteristics of the food's raw material.
- (t) Quality control procedures - the planned and systematic activities implemented within the quality system and demonstrated as needed to provide adequate confidence that those responsible for the fortification of fortified food/food products will fulfill requirements for quality particularly fortification.
- (u) Recommended Dietary Allowance (RDA) - levels of nutrient intakes, which are considered adequate to maintain health and provide reasonable levels of reserves in the body tissues of nearly all healthy persons in the population.
- (v) Refined sugar - raw sugar and that has undergone processing to produce white, crystalline sugar used for household consumption and as an ingredient for processed food including white refined sugar derived from sugar beets and sugar containing flavoring or coloring matter wherein sugar content is over 65% by dry weight. For purposes of this IRR, refined sugar substitutes which can be fortified such as but not limited to Very High Pol Low Color sugars (e.g. Brazilian whites), Plantation whites and sulphitated white shall be considered as refined sugar.
- (w) Repacker - may be a manufacturer, tolee or distributor that packs food products from bulk packaging to retail packaging.
- (x) Sangkap Pinoy Seal Program - a strategy to encourage manufacturers to fortify processed foods or food products with essential nutrients at levels approved by the DOH. The fundamental concept of the program is to authorize manufacturers to use the DOH seal of acceptance for processed foods or food products, after these products passed a set of defined criteria. The seal is a guide used by consumers in selecting nutritious foods.
- (y) Staple food - basic food normally consumed by the general population on a daily basis e.g. rice, flour, sugar, oil.

- (z) Tollee – any person, whether natural or juridical, including a trader, buyer or seller, repacker, or even the producer, who owns the raw materials such as raw sugar, palay, crude vegetable oil and wheat grains and engages the refinery or miller for the purpose of refining or milling for a fee, i.e., the tolling fee.
- (aa) Unprocessed food – food that has not undergone any treatment that results in substantial change in the original state even if it may have been divided, boned, skinned, cut cleaned, trimmed, fresh-frozen or chilled.
- (bb) Wheat flour – a powdery product primarily made from milling wheat grains.

RULE IV - THE PHILIPPINE FOOD FORTIFICATION PROGRAM

SECTION 1. The Philippine Food Fortification Program shall cover all imported or locally processed foods or food products for sale or distribution, for human consumption in the Philippines, except as provided in Sec. 2 of Rule X of this IRR.

SECTION 2. The Philippine Food Fortification Program shall consist of two systems:

- a. Voluntary food fortification to encourage food processor to undertake food fortification on their own volition to enhance the nutrition content of their food products;
- b. Mandatory food fortification for specific food products enumerated in Sec. 6 of Republic Act No. 8976 and those that may be required by the National Nutrition Council (NNC) to be fortified under the same section thereof;

SECTION 3. Pursuant to the above, the Implementing Rules and Regulations shall apply to all manufacturers, or producers, importers, traders, tollees, retailers, repackers of food products covered by Sec. 2 of Rule IV of this IRR, as well as restaurants and food service establishments where such food products are encouraged to be served.

SECTION 4. The above named business establishments enumerated in the preceding section except food service establishments shall be duly licensed with the concerned government agencies, such as National Food Authority for rice, BFAD for wheat flour, Sugar Regulatory Administration for sugar and Philippine Coconut Authority for cooking oil. They shall likewise inform BFAD prior to the process of fortification and they shall register their products with BFAD prior to distribution.

SECTION 5. The above-named government agencies shall enter into a Memorandum of Agreement with the Bureau of Food and Drugs regarding the licenses mentioned in the preceding paragraph.

RULE V - VOLUNTARY FOOD FORTIFICATION

SECTION 1. Under the Sangkap Pinoy Seal Program (SPSP) the Department of Health (DOH), shall encourage the fortification of all processed foods or food products based on the rules and regulations which the DOH through BFAD shall issue after the effectivity of this Act.

SECTION 2. Manufacturers who opt to fortify their processed food or food products but do not apply for registration under the Sangkap Pinoy Program, shall fortify their processed foods or food products based on acceptable standards on food fortification set by the DOH through BFAD.

SECTION 3. The addition of micronutrients to processed foods or food products to avoid over or under fortification shall be based on DOH guidelines for food fortification embodied in DOH Administrative Order No. 4-A series of 1995 and such other necessary guidelines that may be issued by DOH in consultation with the concerned industry and /or government agencies.

RULE VI - MANDATORY FOOD FORTIFICATION

SECTION 1. The following staple food products shall be fortified in accordance with standards set by the DOH through BFAD, except as provided in Section 2, Rule X as follows:

- (1) All rice, except brown rice and locally produced glutinous rice, to be fortified with iron. For this purpose, the DOH through BFAD, in consultation with the National Food Authority and the Philippine Confederation of Grains Association (PHILCON), hereby sets the minimum standard for rice fortification to wit:

Fortificant	Minimum Acceptable Level	Maximum Tolerable Level
Iron Ferrous Sulfate	60 mg Fe/kg raw rice	90 mg Fe/kg raw rice
Others approved by DOH/BFAD	Levels set by BFAD	Levels set by BFAD

- (2) Wheat flour to be fortified with Vitamin A and iron. The DOH through BFAD, in consultation with the Philippine Association of Flour Millers and the Philippine Chamber of Flour Manufacturers, hereby sets the minimum standards for wheat fortification, to wit:

Fortificant	Minimum Acceptable Level	Maximum Tolerable Level
Vitamin A Retinol palmitate/acetate	3.0 mg/kg as retinol	6.5 mg/kg as retinol
Or others approved by BFAD	Levels set by BFAD	Levels set by BFAD
Iron Elemental Iron (electrolytic, H reduced, particle size should be ≤ 50 microns)	70.0 mg Fe/kg	105 mg/kg as retinol

Ferrous Sulfate or Ferrous Fumarate	50.0 mg Fe/kg	75.0 mg Fe/kg
Others approved by BFAD	Levels set by BFAD	Levels set by BFAD

- (3) Refined sugar for human consumption to be fortified with vitamin A. The DOH through BFAD, in consultation with Sugar Regulatory Administration (SRA) and sugar industry organizations, hereby sets the minimum standards for refined sugar fortification, to wit:

Fortificant	Minimum Acceptable Level	Maximum Tolerable Level
Vitamin A Retinol Palmitate	5.0 mg/kg	30.0 mg/kg
Or others approved by BFAD	Levels set by BFAD	Levels set by BFAD

- (4) Cooking oil for human consumption to be fortified with vitamin A except for export. The DOH through BFAD in consultation with the Philippine Coconut Authority (PCA), the United Coconut Association of the Philippines (UCAP), the Coconut Refiners Association (CORA), and the Philippine Coconut Research and Development Foundation (PCRDF) hereby sets the minimum standards for the level of fortification of cooking oil, to wit:

Fortificant	Minimum Acceptable Level	Maximum Tolerable Level
Vitamin A Retinol palmitate	12.0 mg RE/L	23 mg RE/L
Or others approved by BFAD	Levels set by BFAD	Levels set by BFAD

- (5) Other staple food products shall be fortified with appropriate nutrients as may be required by the National Nutrition Council (NNC) when nutrition surveys show the need for fortification of such other staple food, and scientific findings show the feasibility of fortifying such food products.
- (6) Such food fortification that may be required by the NNC does not need further legislation but only through regulations to be promulgated by the DOH through BFAD, in consultation with other concerned agencies and industry organizations.

SECTION 2. The mandatory fortification of the four identified staple foods shall be the responsibility of the following:

- a. Locally processed staple food products shall be fortified by the manufacturers.

In case the manufacturer is not the owner of the raw sugar, crude vegetable oil, palay and wheat grains, the tollee shall be responsible for notifying the refinery or the miller of the destination of the processed food, whether for export, for the production of other processed food products, or for direct human consumption. In case fortification of the mandatory staple was not required by the tollee, and the latter nevertheless sells or distributes the same in cases where fortification is required under these rules, said tollee shall be responsible for the non-fortification of the mandatory staple. Likewise, the miller or refiner shall be responsible for reporting monthly to BFAD any non-fortification required by the tollee.

- b. For imported staple food products, food fortification shall be done by the manufacturer at the place of manufacture. If such imported products are not fortified at the source of manufacture, the importers thereof shall be responsible for their food fortification before they are released for sale or distribution in the Philippines.
- c. Repackers shall repack only staple food products that have been fortified.

SECTION 3. The label of fortified staple food products offered for sale in the market shall include a statement of the fortificant added and the amount present within the shelf life of the product.

RULE VII - QUALITY ASSURANCE

SECTION 1. In accordance with the mandate of Sec. 7 of Rep. Act No. 8976, the agencies responsible for the implementation of this law shall establish a quality assurance system with respect to food fortification. However, manufacturers and importers of processed food or food products or repackers shall also establish their own quality assurance system, which shall conform to the quality assurance system of the implementing agency. Annex 1 is the General Quality Assurance system for Food Fortification to be used as a guide.

RULE VIII - IMPLEMENTATION, MONITORING AND REVIEW

SECTION 1. The DOH through BFAD is the lead agency in the implementation and monitoring of this Act. The DOH shall lead in planning the activities on food fortification which shall include the promotion and advocacy activities on the use of fortified food products through its Sangkap Pinoy Seal Program and other programs to promote nutrition. Products that have been accepted under the Sangkap Pinoy Seal Program can use the SPSP seal.

SECTION 2. The DOH, is authorized to charge reasonable fees and under authority of Sec. 8 of Rep. Act No. 8976 shall use the fees collected under the SPSP for promotional and advocacy activities for nutrition. Likewise, BFAD is also authorized to collect reasonable fees for the registration of fortified products.

SECTION 3. The NNC, as the policymaking and coordinating body on nutrition shall serve as the advisory body on food fortification. As such, the NNC shall conduct a periodic review at least once every five years, or upon petition of an industry mandated

to fortify their products, of the micronutrient added to food, to determine if mandatory food fortification is still needed or not. The NNC shall use the data of the Food and Nutrition Research Institute (FNRI) national nutrition survey and/or the assessment of the Philippine Plan of Action on Nutrition (PPAN), and other nutrition surveillance systems in conducting such review.

SECTION 4. The DOH through BFAD, as the lead implementing agency shall be assisted in the monitoring and review of the program by the following:

- a. Sugar Regulatory Administration (SRA) for sugar;
- b. National Food Authority (NFA) for rice;
- c. Philippine Coconut Authority (PCA);
- d. Bureau of Customs for imported products
- e. The other agencies enumerated in Rule No. IX.

The BFAD shall continue to monitor and review the fortification of wheat flour.

SECTION 5. The BFAD shall formulate the standard operating procedures (SOP) for monitoring the implementation of this Act.

SECTION 6. The Local Government Units (LGUs) shall assist in the monitoring of foods mandated to be fortified, in public markets, retail stores, and food service establishments. It shall likewise check if the labels of fortified products contain nutrition facts stating the nutrient added and its quantity. The LGUs shall designate only one set from the following officials enumerated in Rep. Act No. 8976, Sec. 8 to conduct the monitoring or checking functions:

Health officers or
Agricultural officers or
Nutritionist-dieticians or
Sanitary Inspectors

The LGUs shall inform BFAD which of the officers enumerated above as been assigned to monitor the fortified products.

The LGUs shall submit reports on monitoring to the Bureau of Food and Drugs (BFAD) in the manner and form prescribed by the latter.

SECTION 7. The business establishments in the local food industries and importers of processed foods covered by this Act shall submit to the DOH the following:

- a. Annual Reports, indicating their industrial concerns relative to food fortification,
- b. Production, marketing and distribution of food-fortified products that they are manufacturing.

SECTION 8. The Bureau of Customs shall inform the DOH through BFAD of all imported rice, sugar, wheat flour and cooking oil, prior to their release, to enable BFAD to ascertain if such imported products are already fortified. BFAD shall undertake a final inspection that the products are really fortified and registered with BFAD as fortified products prior to sale and distribution.

RULE IX - SUPPORT TO AFFECTED MANUFACTURERS

SECTION 1. The affected manufacturers shall be supported by the following government agencies in the achievement of the purposes of this Act, through their respective programs:

- a. The Department of Trade and Industry (DTI) shall assist and support affected manufacturers in upgrading their technologies by helping them obtain soft loans and financial assistance for the procurement of technologies and machines. Through the Board of Investments (BOI), the DTI shall provide incentives by including food fortification as a priority investment or activity. The incentives may include but not be limited to exemption from customs duties and national internal revenue taxes on imported capital equipment and spare parts and inputs required in fortifying food products, tax credits on the portion of food products fortified, tax credit on domestic capital equipment and/or spare parts equivalent to the normal duty imposed on their imported counterpart.
- b. The Department of Science and Technology (DOST) shall assist the affected manufacturers by developing and implementing comprehensive program for the acquisition, design and manufacture of new machines and technologies and transfer said machines and technologies to manufacturers.
- c. The Land Bank of the Philippines (LBP) and the Livelihood Corporation (LIVECORP) shall grant loans at preferential rates of interest to manufacturers of fortified food products.
- d. Manufacturers of food-fortified products under the mandatory and voluntary food fortification program may avail of the analytical laboratories of government agencies and institutions for nutrient analysis at a reasonable cost. Such agencies and institution, like the Department of Agriculture, National Food Authority, Philippine Coconut Authority, Sugar Regulatory Administration and attached agencies with accredited facilities shall assist the manufacturers of fortified food products.
- e. Incentives in the form of tax credits may also be granted by the Department of Finance thru the Bureau of Internal Revenue to business establishments that undertake food fortification before the effectivity of mandatory food fortification.

SECTION 2. The agencies mentioned in Rule VIII and Rule IX mandated to implement and support the food fortification program shall allocate part of their budget for the implementation and support of this program.

RULE X - NONCOMPLIANCE WITH FORTIFICATION PROCESS

SECTION 1. The following acts shall be considered as noncompliance with the food fortification process:

- a. If the food fortification level does not comply with the requirements as mentioned in Rule VI, Section I except when the deviation from the fortification levels are justified and are properly declared on the label of the product.

- b. If the fortificant used is different from that approved by the DOH/BFAD, and
- c. If the process of fortification does not conform to Rule VII of this IRR.

SECTION 2. The above provisions notwithstanding, exceptions subject to the approval by BFAD, may be allowed as in the following cases:

- (a) Dietary supplements for which established standards have already been prescribed by the DOH through BFAD;
- (b) Those intended for exports or for use in the production of other processed food products, such as beverages where the fortified product used for food processing may affect the processed product by the fortificant.

RULE XI - ADMINISTRATIVE SANCTIONS

SECTION 1. Noncompliance of RA 8976 including the food fortification guidelines set by the DOH through BFAD shall entitle the latter to impose any or all of the following applicable administrative sanctions, after due notice and hearing:

- a. The DOH through BFAD shall deny registration of new processed foods and staple food products that do not comply with the food fortification requirements. The DOH through BFAD shall not allow said products to be sold in the market.
- b. The DOH through BFAD shall order the owners or sources of the products to recall or withdraw the said processed foods or food products from the market, if already in the market for sale and distribution.
- c. For the first violation of Republic Act No. 8976, or the Implementing Rules and Regulations or the fortification standards or guideline, the DOH through BFAD shall impose a fine of not less than Three Hundred Thousand Pesos (P300,000); and suspension of registration of the products.
- d. For the second violation, the DOH through BFAD shall impose a fine of not more than Six Hundred Thousand Pesos (600,000) but not less than Three Hundred Thousand One Pesos (P300,001) and suspension of the product registration.
- e. For the third violation, the DOH through BFAD shall impose a fine of not more than One Million Pesos (P1,000,000) but not less than Six Hundred Thousand One Pesos (P600,001) and cancellation of the product registration.
- f. If the violator is a juridical entity, the person responsible for the violation, shall be jointly and solidarily liable with the juridical entity, for the administrative fines imposed in the above provisions.

SECTION 2. When the act or omission in violation of Rep. Act 8976 and/or its Implementing Rules and Regulations is attended by a manifest intention to mislead, defraud or deceive the consuming public, the maximum fine and revocation of the License to Operate and License to Sell shall be imposed.

SECTION 3. In case of appeal from the decision of BFAD, the Secretary of Health may delegate the conduct of the administrative investigation of any violation of RA 8976 or its Implementing Rules and Regulations to an adjudication board composed of the following members from:

- a. Bureau of Food and Drugs (BFAD) as Chairman
- b. Department of Interior and Local Government
- c. Department of Trade and Industry (DTI)
- d. An official from the Sugar Regulatory Administration (SRA) or National Food Authority (NFA) or Philippine Coconut Authority (PCA) or Bureau of Food and Drugs (BFAD), as the case may be, when the investigation involves sugar, rice, cooking oil or wheat flour, respectively, and
- e. A representative nominated by the industry organization whose product is the subject of investigation, provided however, that such representative is not personally involved in the matter under investigation. Any further action a party may decide to take in connection with the decision of the adjudication board, shall be subject to the rules and procedures of the BFAD.

RULE XII - INTERNATIONAL COMMITMENTS

SECTION 1. Nothing in this Act is intended to violate provisions of Treaties and International Agreements to which Philippines is a party.

RULE XIII - REPEALING CLAUSE

SECTION 1. All Administrative Orders, circular and rulings on food fortification issued by the DOH and/or BFAD and other agencies involved in nutrition regulation that are inconsistent or contrary to the provisions of Rep. Act No. 8976 or the Implementing Rules and Regulations shall be considered hereby repealed or amended.

RULE XIV - SEPARABILITY CLAUSE

SECTION 1. If any part of these rules and regulations shall be declared null and void by a court having jurisdiction, the other portions thereof shall remain legal and valid and in full effect.

RULE XV - AMENDMENTS

SECTION 1. The provision of these Implementing Rules and Regulations shall be amended in the same manner that they were formulated, calling for consultative meetings of the same agencies involved in the formulations of the IRR as provided in Sec. 12 RA No. 8976.

RULE XVI - EFFECTIVITY

SECTION 1. The Implementing Rules and Regulations shall take effect thirty (30) days after its publication in a newspaper of general circulation with respect to Voluntary Food Fortification.

SECTION 2. The Implementation of the Mandatory Food Fortification for wheat flour, refined sugar, cooking oil and rice, including those milled and/or distributed by

the National Food Authority, shall commence after four years from the effectivity of Rep. Act No. 8976, which was November 7, 2000, hence the Implementing Rules and Regulations for Mandatory Food Fortification shall take effect on November 7, 2004.

APPROVED:

MANUEL M. DAYRIT, M.D., M.Sc.
Secretary of Health

Date Published _____
Publication _____

Annex 1

General Quality Assurance System for Food Fortification

The quality assurance system of the manufacturers and importers in the fortification of food products should include or address the following:

- 1. Imposing quality control on the fortificant(s) to ensure that specifications are met**
 - 1.1 require certificate of analysis for every delivery of the fortificant(s)
 - 1.2 checking if the fortificant(s) used is still within the market shelf-life

- 2. Identifying quality control measures for fortificant(s)' handling and storage**
 - 2.1 fortificant(s) properly sealed and stored in a cool dry place
 - 2.2 sensitive fortificant(s) in packing size that can be consumed for one batch of product or for one day's production
 - 2.3 one package of fortificant(s) good for several batches produced within a few days i.e., not more than one week
 - 2.4 fortificant(s) properly weighed and appropriate records maintained
 - 2.5 weighed fortificant(s) properly handled; used within a day
 - 2.6 container source of the fortificant(s) immediately sealed after weighing and stored in a cool dry place

- 3. Establishing/Identifying quality control on the fortification process**
 - 3.1 equipment used appropriate for product being fortified
 - 3.2 mixing method as described is an approved production process
 - 3.3 mixing time observed and recorded

- 4. Routinely undertake analyses of the fortification level of the fortified products (indicating frequency)**
 - 4.1 in-house analysis of the fortificant(s) in the finished product
 - 4.2 analysis done by external laboratories

- 5. Conduct equipment calibration**
 - 5.1 equipment measuring devices calibrated as scheduled
 - 5.2 calibration records maintained

- 6. Putting in place a recall system in case a product recall is needed**
 - 6.1 Identifying fortified product by its lot identification code.

- 7. Record keeping of all the quality control activities for the fortified products**