

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY San Lazaro Compound, Rizal Avenue, Manila Telephone No: 743-83-01 to 23 loc. 1125-1126

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DEPARTMENT CIRCULAR

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TO : THE UNDERSECRETARIES, ASST. SECRETARIES, CHD/BUREAU/SERVICE PROJECT/PROGRAM DIRECTORS, MEDICAL CENTER CHIEFS OF SPECIAL/SPECIALTY HOSPITALS, EXECUTIVE DIRECTOR OF DANGEROUS DRUGS BOARD, PRESIDENT OF THE PHIC AND OTHERS CONCERNED

SUBJECT : <u>Revised Implementing Rules and Regulations of Republic</u> Act No. 8172 "An Act Promoting Salt Iodization Nationwide and for Related Purposes"

Attached for information and guidance is a copy of the Revised Implementing Rules and Regulations of Republic Act No. 8172 "An Act Promoting Salt Iodization Nationwide and for Related Purposes".

Dissemination of the information to all concerned is desired.

By authority of the Secretary of Health:

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Republic of the Philippines Department of Health OFFICE OF THE SECRETARY San Lazaro Compound, Rizal Avenue, Manila Telephone No: 743-83-01 to 23 loc. 1125-1126

REVISED IMPLEMENTING RULES AND REGULATIONS OF REPUBLIC ACT NO. 8172 "AN ACT PROMOTING SALT IODIZATION NATIONWIDE AND FOR RELATED PURPOSES"

The 1996 Implementing Rules and Regulations of RA 8172 (ASIN Law) is hereby revised to conform with developments to strengthen and fast track implementation of the Law and ensure that only iodized salt for human and animal consumption is available in the country.

RULE I COVERAGE

SECTION 1. These Rules and Regulations shall apply to:

- a) all producers/manufacturers, repackers, importers, traders, distributors, and retailers including public market vendors of salt for human or animal consumption;
- b) all food service establishments where food is being served or sold;
- c) all food manufacturers/processors using salt in their manufacturing processes;
- d) all local government units (LGUs);
- e) all other government agencies;
- f) all non-government agencies and related professional organizations involved in nutrition; and
- g) all government and private hospitals and other institutions.

RULE II INTERPRETATION

- **SECTION 1.** These Rules and Regulations shall be construed in a manner that can achieve the purposes of the ASIN Law, namely:
 - a) to contribute to the elimination of micronutrient malnutrition, particularly iodine deficiency disorders;
 - b) to ensure that only iodized salt is available in the market for human and animal consumption.
 - b.1. require salt producers/manufacturers, importers, to iodize the salt they manufacture, produce, distribute, trade and/or import;

- b.2. require salt repackers to repack and sell only iodized salt;
- b.3. require distributors, retailers, and vendors to distribute or sell only iodized salt;
- b.4. require food processing and food service industries to use only iodized salt;
- b.5 require food service establishments to use only iodized salt in the food they serve.
- c) to require the national and local governments to perform their roles and responsibilities in implementing the act through the:
 - c.1. provision of necessary resources;
 - c.2. provision of mechanisms and incentives for the salt industry
 - c.3. strict enforcement of the salt iodization program,
 - c.4. conduct of massive public information campaign
 - c.5. enactment and enforcement of ordinances to require compliance of manufacturers, importers, repackers, distributors, retailers, restaurants and food establishments
- d) to ensure the sustainability of the salt iodization program through the concerted effort of all agencies as enumerated in Rule I and Rule VI hereof.

Any question or doubt as to the intent and meaning of the provisions shall be construed or resolved in accordance with the Policy and Purposes as provided in the ASIN Law.

RULE III DEFINITION OF TERMS

In the implementation of the ASIN Law, the following terms shall be construed in accordance with the general definitions provided in Section 4 of the Act, to wit:

- a) Center for Health Development (CHD) refers to the former Regional Office of the Department of Health (DOH)
- b) Distribution means the exchange, transmittal, conveyance, consignment, supply, delivery, trade, sale, or disposal of food-grade salt, whether for remuneration or other considerations.
- c) Distributor refers to a person or an establishment, which distributes, sells or imports salt for distribution to retailers, other outlets.
- d) Fortificant in relation to the process of salt iodization, the term refers to potassium iodate or other suitable fortificant, provided it is recommended and approved by DOH-BFAD, taking into consideration the circumstances of quality, effectiveness, stability, availability and new discoveries that can facilitate salt iodization in the most effective and economic manner.

- e) Food fortification refers to addition of nutrients to processed foods at levels above the natural state.
- Food-grade salt refers to salt for human and animal consumption as distinguished from industrial salt.
- g) Food manufacturers/processors refers to the business/enterprise of manufacturing or processing food using salt in their products.
- h) Food service establishments refers to hotels, restaurants, carinderias, catering firms, hospitals, canteens and other similar outlets which serve or sell food to consumers.
- i) Importer one who buys salt from outside the country.
- j) Industrial salt refers to salt used in the treatment, processing and/or manufacture of non-food commercial products.
- k) Iodized salt ordinary salt with fortificant Potassium Iodate (K103) as defined in item d.
- Iodine deficiency disorders a broad spectrum of manifestations resulting from lack of iodine in the diet which leads to the reduction of intellectual and physical capacity affecting everyone who is iodine deficient and may manifest as goiter, mental retardation, physical and mental defects and cretinism.
- m) Label any written, printed or graphic matter upon any article or any of its container or wrappers or accompanying the packaged food, that describes the product.
- n) Licensing the process of securing from the Bureau of Food and Drugs (BFAD) a license as manufacturer, producer, trader or importer of iodized salt, Provided that the importer shall also secure a license to manufacture and iodize the imported salt.
- o) Manufacturer as used in this IRR, one who produces, imports, trades in and distributes salt which is categorized as follows:
 - Large producer/manufacturer one who produces, imports, trades and/or distributes and sells salt exceeding two thousand metric tons (2,000 MT) per year.
 - Medium producer/manufacturer one who produces, imports, trades in, distributes, sells salt ranging from more than three hundred metric tons (300 MT) to two thousand metric tons (2,000 MT) per year.

- Small salt producer/manufacturer one who produces, trades in or distributes/sells salt ranging from more than two metric tons (2 MT) to three hundred metric tons (300 MT) per year.
- 4. Subsistence producer/manufacturer one who produces, trades in or distributes salt not exceeding two metric tons (2 MT) of salt per year.
- p) Method refers to the scientifically accepted technique that is perceived to bring about the best and most effective way of salt iodization.
- q) Micronutrient malnutrition refers to a disorder resulting from deficiencies in vitamin A, iron, iodine and other micronutrients which the body needs in minute quantities every day.
- r) Registration the process of acquiring from the BFAD a certificate of product registration (CPR).
- s) Regulatory requirements the provisions of all applicable laws, regulations, executive orders, and other enactments related to food quality and safety, purity, nutritional composition, and other aspects of food regulations and control. In applying or interpreting the regulatory requirements, reference may also be made to scientifically accepted standards or regulations.
- t) Repacker one who packs iodized salt from bulk packaging to retail packaging in furtherance of distribution of food or one who buys and repacks using its own label.
- u) Salt industry refers to the business sector engaged in the production, distribution, trading, retailing and importation of salt.
- v) Salt iodization the addition of iodine to salt intended for human and animal consumption in accordance with specifications as to form, fortificant, method, manner and composition as may be prescribed by the BFAD of the DOH.
- w) Salt Iodization Advisory Board (SIAB) is the policy and coordinating body for the national salt iodization program, composed of members of the National Nutrition Council (NNC) Governing Board, including a representative each from the Department of Environment and Natural Resources (DENR), the medical profession, and salt manufacturers.
- x) Signage any written, printed or graphic material not less than 81/2 x 11" in size stating that the establishment uses iodized salt in their food products in compliance with the ASIN Law.

- y) Stores/Markets refers to department stores, shops, groceries, mini-marts, sarisari stores, wet markets and other outlets which sell wholesale or retail iodized salt to consumers.
- z) Trading refers to the buying and selling of food-grade salt by wholesale or retail.

RULE IV STANDARDS AND REQUIREMENTS

SECTION 1. The BFAD of DOH hereby prescribes the following standards for iodizing salt in the Philippines.

COMPOSITION AND STANDARDS

Purity requirements

Identification	positive for Sodium and Chloride
Assay, min	97% (dry basis)
Moisture, max	4% for refined salt
	8% for unrefined salt
Calcium & Magnesium, max 2%	
Arsenic, max	1.0 mg/kg
Cadmium, max	0.5 mg/kg
Lead, max	2.0 mg/kg
Mercury, max	0.2 mg/kg

The salt may contain natural secondary products which may include calcium, potassium and magnesium compounds.

Iodine levels

Source	Type of container/package	
	Bulk (>2kgs)	Retail (<2kgs)
Locally produced salt	70.160 /	CO 100 4
Production site Retail site	70-150 mg/kg 50-100 mg/kg	60-100 mg/kg 40-100 mg/kg
Imported salt	70-150 mg/kg	60-100 mg/kg

In case iodized salt will be used in processing food products, the iodine level can exceed the above standard level to allow for losses of iodine in processing.

Such standards shall be reviewed and updated annually by the BFAD in consultation with the SIAB and other concerned parties.

- **SECTION 2.** Failure to comply with the quality specifications and labeling requirements prescribed in the standards shall mean a violation of the provisions on adulteration and misbranding under Sections 14 and 15 of RA 3720, otherwise known as the Food, Drugs and Cosmetics Act, as amended, and the relevant provisions of RA 7394 otherwise known as the Consumer Act of the Philippines.
- **SECTION 3**. At the production level, all manufacturers of iodized salt shall ensure the quality of iodized salt prior to distribution. Such activities shall include, but shall not be limited, to the following:
 - a) Iodine levels testing: at regular intervals on a daily basis, samples of iodized salt shall be collected from the production line and tested for iodine content using the titration method and/or iodine test kits.
 - b) Equipment inspection: at least twice daily to ensure its proper operation.
 - c) Mixing process shall be monitored regularly to ensure consistent mixing and homogeneity of iodine content in the batch being processed.
 - d) Monitoring of salt ready for distribution: each lot shall be sampled to ensure the integrity of the salt in the package.
 - e) Packaging and labeling inspection shall be routinely conducted to ensure conformity to prescribed labeling requirements.
 - f) Record keeping: daily control charts and weekly summaries of activities and corrective actions taken shall be maintained for a period of at least 12 months from date of manufacture. Manufacturers of iodized salt shall provide traders with a Salt Iodization certification indicating the iodine level of the specified Batch No. traded or lot sold to the traders and the date of iodization.
- SECTION 4. Iodized salt shall be distributed and sold according to the principle of first in, first out. Iodized salt sold at retail or final distribution points beyond twelve (12) months from date of iodization shall be considered expired. Expired iodized salt shall not be sold nor distributed for human and animal consumption but instead be returned to the last seller or distributor for re-iodization.

- SECTION 5. The DOH through BFAD, shall put in place a system to monitor the quality of iodized salt in collaboration with the LGUs, DILG and other local law enforcement agencies i.e. Philippine National Police (PNP), Coast Guard, DENR, Philippine Ports Authority (PPA), Land Transportation Office (LTO). It shall also seek the assistance of the LGUs and the Bureau of Customs under the Department of Finance (DOF) to determine the volume of production and sale of the locally manufactured and imported iodized salt, respectively.
- SECTION 6. Importation of industrial salt shall be in bulk, never in bags or sacks. Imported salt in bulk shall be released to the importers' warehouse for iodization, if it is to be sold for human or animal consumption, and shall be inspected by BFAD after iodization, otherwise it cannot be sold or distributed until iodized.

Importers of salt shall submit to BFAD, prior to the arrival of shipment, a non-negotiable copy of Bill of Lading, Commercial Invoice and packing list, if any. In all cases, BFAD shall endeavor that the above transactions are not delayed.

No imported salt shall be released from BOC unless BFAD issues clearance.

- **SECTION 7.** Only iodized salt shall be imported in bags or sacks, subject to inspection by BFAD upon arrival. If iodine level is below Philippine standards, the importer shall iodize it to conform to Philippine standards. However, pure vacuum dried salt, because of its nature, can be imported in bags or sacks, provided that, if they are to be used for human or animal consumption, it shall be iodized by the importer prior to release to market.
- **SECTION 8.** Salt manufacturers/producers, traders, retailers, repackers and stores/markets shall provide the proper identification/labels of iodized salt during display at retail.
- SECTION 9. All food manufacturers and producers shall utilize iodized salt in their products except when the use of iodized salt will have an adverse effect on a specified product. In such cases, the food manufacturers/producers shall present proof to BFAD that the use of iodized salt has adverse effect on their food products. Such proof shall serve as basis for exemption from compliance with Section 5(e) of RA 8172 (ASIN Law). BFAD shall submit to the SIAB a list of food manufacturers utilizing iodized salt and those with definite exemption, and shall update this list annually. BFAD shall provide a list of recognized laboratories that can assess the claims.

SECTION 10. All food manufacturers and processors shall include a label on the use of iodized salt in their food products.

SECTION 11. BFAD and Department of Science and Technology (DOST) shall establish a data base on salt iodization.

RULE V

LICENSING OF SALT MANUFACTURERS AND SALT IMPORTERS/ DISTRIBUTORS AND REGISTRATION OF IODIZED SALT

- **SECTION 1.** License to Operate (LTO). All salt producers, manufacturers, traders, repackers and importers shall secure an LTO as manufacturer from BFAD in compliance with prescribed documentary and technical requirements (Annexes 1-2). The importers must comply with the technical requirements and the imported salt shall be subject to registration and monitoring. BFAD may delegate to the DOH-CHDs its authority to renew/revalidate LTOs.
- **SECTION 2.** Product Registration. All salt (locally manufactured & imported) shall be registered with BFAD. Imported non-iodized salt shall be iodized by the importer prior to its sale to the public. If iodization was done by importer the latter shall issue such Salt Iodization Certification, identifying the firm that iodized the salt. Importers of salt shall secure a Salt Iodization certification from its suppliers if the salt they imported are iodized.
- SECTION 3. Failure to secure the LTO required above shall be subject to sanctions under Rule VIII.

RULE VI

ROLES OF AGENCIES CONCERNED IN THE SALT IODIZATION PROGRAM

SECTION 1. The DOH, as the lead agency in the implementation of this Act, shall:

- a) set and enforce standards for food-grade iodized salt and monitor compliance thereof by the food-grade salt manufacturers/importers, distributors and traders, as specified in Section 2, Rule VIII, through BFAD;
- b) provide training on salt iodization technology and quality assurance through its Centers for Health Development in coordination with the DOST and the Technology and Livelihood Resource Center (TLRC);

- c) spearhead a public information drive in cooperation and coordination, with the LGUs and other agencies particularly the Department of Education (DepED), Philippine Information Agency (PIA), Provincial Science and Technology Centers (PSTC) of the DOST, private sector and students. All sectors in the salt industry shall also assist in such information campaign through tri-media and all other social marketing activities for a systematic and sustained public information campaign; and
- d) set-up and maintain a functional monitoring and evaluation system, in cooperation with LGUs and other agencies;
- **SECTION 2.** The Local Government Units (LGUs) shall support the development and sustainability of the Salt Iodization Program in coordination with the Department of Interior and Local Government (DILG). They shall:
 - a) enact and enforce local ordinances to support the implementation of the ASIN Law by requiring all outlets, supermarkets, wet markets and vendors to sell only iodized salt, salt producers to iodize the salt they produced and food service establishments such as restaurants to use iodized salt and to display in their premises the proper signage that they use iodized salt for all their food products;
 - b) monitor the presence of iodine in salt as provided in Section 2, Rule VIII, through its respective market inspectors/supervisors, health officers, nutritionist-dietitians, sanitary inspectors and/or any official designated by the local chief executive;
 - c) establish and maintain a list of salt producers, importers and distributors in their respective territorial jurisdiction. A list of registered salt producers, importers and distributors in every province shall be submitted to BFAD within six (6) months from the effectivity of this revised IRR. The list shall reflect the following information per salt producer/manufacturer, importer or distributor:
 - 1. Name and address of company and/or owner/producer/ importer or distributor;
 - 2. Location of salt production site (sitios/barangay) or warehouse;
 - 3. Annual production capacity (in metric tons) or importation;
 - 4. Types of salt produced/imported or distributed:
 - food-grade (course or fine)
 - iodized salt
 - non-iodized salt (industrial)
 - 5. Distribution channels, such as:
 - direct selling to consumers within the province
 - traders within the province
 - traders from other provinces/regions

- food manufacturers within the province
- food manufacturers outside the province/regions
- d) provide budget for the implementation of ASIN Law and its IRR;
- e) assist in organizing salt producers into cooperatives;
- f) provide semestral accomplishment report to the DOH-CHD copy furnished to BFAD, for the first three years from approval of the IRR.;
- g) assist other government agencies in the implementation of the salt iodization program.
- **SECTION 3.** The Department of Trade and Industry (DTI) shall assist and support local salt producers/manufacturers in upgrading their production technologies by helping them obtain soft loans and financial assistance for the procurement of salt iodization machines, packaging equipment and technology, fortificants, and by ensuring the systematic distribution of iodized salt in the market. Specifically, it shall:
 - a) monitor the price and supply situation of iodized salt in accordance with RA 7581 otherwise known as the Price Act;
 - b) provide incentives to the salt industry by including salt iodization as a priority investment program of the government through its Board of Investments;
 - c) assist salt producers/manufacturers obtain soft loan for machines, equipment and other materials such as fortificant and other chemicals needed to upgrade the salt industry, through its Small Business Guarantee and Finance Corporation (SBGFC);
 - d) provide assistance to salt producers/manufacturers on matters of package design and packaging technology through its Product Development and Design Center of the Philippines (PDDCP); and
 - e) draw out recommendations/mechanisms to facilitate production and distribution of iodized salt for human and animal consumption.

SECTION 4. The Department of Science and Technology (DOST) shall:

 a) develop and implement an appropriate program for assistance to salt producers/manufacturers in the design and fabrication of salt iodization equipment;

- b) provide technical assistance in the design, maintenance and operation salt iodization machines;
- c) transfer appropriate salt iodization technology to salt producers/manufacturer;
- d) assist in the promotion of iodized salt utilization and consumption;
- e) assist local salt producers in meeting the quality specifications defined in Rule IV, section 1 through promotion of improved methods of producing industrial grade salt from solar evaporation; and
- f) continue to conduct food fortification R & D and related R & D in support of the implementation of R. A. 8172

SECTION 5. The Department of Education (DepEd) shall:

- a) integrate salt iodization and food fortification concepts in the elementary and secondary school curriculum;
- b) monitor the use of iodized salt used in the households through the school children;
- c) require the use iodized salt in the preparation of salt seasoned food items sold at the school canteens, all food establishments within school premises, and food supplements distributed by schools;
- d. promote the use of iodized salt through the Teacher-Child-Parent (TCP) approach of the feeding programs.

SECTION 6. The Technology and Livelihood Resource Center (TLRC) shall:

- a) provide funding assistance to qualified small producers, especially if located in one of the priority provinces in support of the government's poverty alleviation and industry decentralization drive;
- b) develop a program of training entrepreneurs in setting up micro/cottage/small business enterprises to be located in its Technology and Livelihood Development Centers (TLDC) in the provinces;
- c) undertake an all-out information campaign to promote the use of iodized salt nationwide through its tri-media information program and its business

technology courses.

SECTION 7. The Cooperatives Development Authority (CDA) shall:

- a) provide technical assistance to small and subsistence salt producers/manufacturers so that they may organize themselves into cooperatives and undertake salt iodization and marketing of iodized salt in the spirit of cooperativism. The organized cooperatives shall be registered in accordance with the CDA guidelines, rules, regulations and applicable laws; and
- b) encourage registered cooperatives to trade only food grade iodized salt and assist in the promotion of the ASIN Law and monitoring of compliance thereof.

SECTION 8. The Department of Environment and Natural Resources (DENR) shall:

- a) provide assistance to prospective salt producers/manufacturers identifying suitable land areas appropriate for use as salt works/farms. The conversion of such lands into salt farms shall require the concurrence of the landowner and the concerned agency/entity. The DENR shall ensure, through the Environmental Impact Assessment (EIS) System, that the proposed activities near the salt farms do not adversely affect the latter or *vice-versa;*
- b) monitor the adoption of anti-pollution control measures by iodized salt producers/manufacturers;
- c) assist in the promotion of iodized salt;
- d) identify areas not suitable for salt production and monitor contaminants such as, but not limited to arsenic, cadmium, lead and mercury, etc.; and
- e) assist salt farm owners to seek exemption from Comprehensive Agrarian Reform Law (CARL).

SECTION 9. The Bureau of Customs (BOC) of the Department of Finance (DOF) shall:

a) provide BFAD a list of salt importers, and/or consignees on a quarterly basis. In addition, the BOC shall immediately inform BFAD of every entry of salt importation together with their quantities, names and addresses of importers and/or consignees, as soon as the import entry is reported to the BOC. For this purpose, the Commissioner of the BOC shall issue a Customs Memorandum Order (CMO) to all Collectors of Customs in all ports of entry in order that this can be complied with regularly;

- b) hold any imported salt without any clearance from BFAD that the salt imported has been iodized. Furthermore, the BOC shall coordinate with the BFAD authorized personnel in the inspection and/or testing of all imported salt, whether industrial or food grade salt. The BOC can order the release of imported salt, only upon clearance from the BFAD;
- c) hold the release of imported salt that has been found to be not iodized until the salt is iodized. The BOC however, may cause the transfer of the noniodized salt to a bonded warehouse, upon the execution of a bond by the importer, in favor of BFAD. Such bond shall be forfeited in favor of BFAD in the event of non-compliance with the order of BFAD to the importer to have the salt iodized. The cost of iodization and the premium on the bond shall be for the account of the importer; and
- d) cooperate with BFAD in monitoring the entry of salt in all ports of entry and the BOC personnel may be deputized by BFAD in this undertaking.
- **SECTION 10.** Any assistance to salt manufacturers/producers, traders, importers shall take into favorable consideration the size and the capability of such salt producers as well as their faithful compliance with laws on health, labor and employment, environment and ecology.
- SECTION 11. All collaborating agencies, based on their respective functions, shall submit annual accomplishment and semestral progress report on Salt Iodization Program to BFAD-DOH for endorsement to SIAB.

RULE VII ADVISORY BOARD

SECTION 1. The Salt Iodization Advisory Board (SIAB) shall be composed of all members of the NNC Governing Board from, namely the Departments of Agriculture; Health; Social Welfare and Development; Education; Science and Technology; Interior and Local Government; Labor and Employment; Trade and Industry; Budget and Management; the National Economic and Development Authority; its three (3) private sector representatives and a representative each from the DENR, the medical profession and the salt manufacturers, as mandated by Section 8 of the ASIN Law. The chairperson of the NNC Governing Board shall chair the SIAB. The NNC Secretariat shall provide technical and secretariat support to the SIAB.

- SECTION 2. The SIAB shall function as the policy and coordinating body on the national salt iodization program and activities. It shall formulate, coordinate and monitor all activities concerning the salt iodization program from production and marketing to public information campaign. It shall analyze the effectiveness of the salt iodization activities and then evaluate the progress of the program annually based on the reports submitted by DOH and other concerned agencies in the implementation of this Act. The SIAB shall create an executive committee composed of not more than five (5) members who shall be of undersecretary level, to monitor more closely the implementation of the Salt Iodization Program (SIP). The NNC executive committee plus a representative of the salt industry can serve as the SIAB executive committee. The SIAB shall submit an annual report to the Congress of the Philippines on the status of the salt iodization program and offer recommendations for its improvements.
- SECTION 3. The Salt Iodization Advisory Board (SIAB) shall conduct a regular meeting at least once a year.

RULE VIII SANCTIONS

SECTION 1. Applicability – RA 8172(ASIN Law) applies to the entire salt industry including salt producers/manufacturers, traders, repackers, retailers, importers and distributors. It also applies to all food outlets, restaurants and stores and all food processors using food grade salt, Provided that the use of iodized salt shall not prejudice the quality and safety of the food product.

> Authority is given to the BFAD Director to impose sanctions on violators of the law. In addition, the Local Government Units shall provide enabling mechanism to ensure enforcement of the law through ordinances and public information campaigns. Furthermore, they are authorized to impose administrative sanctions and fines to food service establishments, outlets, supermarkets, wet markets, sellers, groceries, vendors and sari-sari stores.

The following guidelines set in place the foregoing procedures to enforce the sanctions of the ASIN Law.

SECTION 2. Locus of Responsibility. Entities within the jurisdiction of BFAD and the LGUs shall include the following:

Local Government Units	Bureau of Food and Drugs
Hospitals	Food processors/manufacturers
Food service establishment	Salt importers
(restaurants, hotels, food chains,	-
catering services, school	
canteens and street food outlets)	
Salt outlets (wet markets, sari-	Salt producers/repackers/distributors/
sari stores)	Traders
Â	Bakeries
	Supermarkets

BFAD may delegate to LGUs its authority to inspect/monitor the above mentioned establishments as to compliance to the ASIN Law. However, issuance of LTOs remains with BFAD unless expressly delegated to the LGU through a MOA with the BFAD Director. The penalty shall be imposed by BFAD on salt manufacturers, importers, repackers, distributors, traders, bakeries, supermarkets, groceries and food processors, and by LGUs to hospitals, food service establishments, salt outlets, stores and other similar salt outlets under its responsibility as listed above.

SECTION 3. Procedures:

The initiation of Administrative Proceedings Against Establishments found violating any of the Provisions of the ASIN Law and this IRR shall be as follows:

- a) For the Bureau of Food and Drugs (BFAD) (See Annex 3 Flow Chart of BFAD Administrative Proceedings)
 - 1. Inspection shall be conducted monthly by duly authorized Food and Drug Regulation Officer (FDRO) in the premises of food processors or manufacturers, salt importers, salt producers/distributors/traders/repackers where any salt is received, held, manufactured, labeled, stored, displayed, delivered, distributed, sold or located or wherever it is reasonably believed these activities are being carried out.
 - 2. Reports on the findings together with a Report of Analysis, if any, shall be submitted to BFAD-Legal Information and Compliance Division (LICD) by duly authorized FDROs.

3. The LICD shall determine if a probable cause for complaint exist. If there is a probable cause, the LICD shall file a complaint with the Office of the BFAD Director.

5.1.2

- 4. A notice shall be sent by BFAD Director to the manufacturer, trader, repacker, retailer/distributor or processor subject of complaint, requiring the filing of an answer which shall be under oath within ten (10) days from receipt of notice to show valid cause in writing why no administrative sanctions shall be imposed for the violation, giving consideration to due process.
- 5. If no answer is received within the prescribed period by BFAD, the case shall be resolved by BFAD Director. If the answer raises factual issues, a hearing shall be conducted.
- 6. If the decision calls for the imposition of fines, and the same has already become final and executory, the LGU may, by authority of the BFAD Director, collect the fine that may be imposed provided that such fine collected shall be held in trust for the exclusive use by the investigating LGU in the implementation of RA 8172 and its IRR.

Fines imposed and collected by BFAD from violators shall accrue to the BFAD for its use in the implementation of ASIN Law pursuant to Sec. 9, RA 8172.

- b) For the Local Government Units (LGU) without Ordinance But With MOA (See Annex 4 – Flowchart of LGU Administrative Proceedings Without Ordinances & with MOA)
 - 1. The Health Officers, Market Inspectors/Supervisors, Nutritionist-Dietitians, Sanitary Inspectors or any official designated by the Local Chief Executive shall conduct inspection on wet markets, sari-sari store, food outlets such as restaurants, hotels, food chains and catering services, as well as other similar establishments under the jurisdiction of LGUs.

The above-mentioned officers may conduct inspection of salt producers/distributors/traders provided they are given authority by BFAD.

- 2. Salt samples that are tested with iodine levels below standards and those negative for iodine, shall be sent to BFAD or the nearest Centers for Health Development formerly Regional Health Offices or other laboratories accredited by BFAD for confirmatory analysis.
- 3. Report on violations shall be submitted by the authorized officer to the Local Chief Executive for information and review, who shall file

complaint and give notice to violator to file an answer within 10 days from receipt.

- 4. If the respondent files an answer, the issue of facts shall be joined and if necessary, a hearing shall be conducted.
- 5. If no answer is received within the prescribed period from the respondent, a decision by the investigating officer confirmed by the Local Government Chief Executive shall be submitted to BFAD Director for review and confirmation.
- 6. The LGU concerned shall prepare recommendatory decision subject to review and confirmation by BFAD Director.
- 7. If the decision calls for the imposition of fines, and the same has already become final and executory, the LGU may, by authority of the BFAD Director, collect the fine that may be imposed provided that such fine collected shall be held in trust for the exclusive use by the investigating LGU in the implementation of RA 8172.
- c) For LGU with Local Ordinance (See Annex 5 Flowchart of LGU Administrative Proceedings with Ordinance)
 - 1. The Health Officers, Market Inspectors/Supervisors, Nutritionist-Dietitians, Sanitary Inspectors or any official designated by the Local Chief Executive shall make the inspection and monitoring of establishment covered by the ordinance.
 - 1.1 The frequency of the inspection would depend on the ordinance or at the discretion of the local chief executive.
 - 1.2 Any private individual or group who has knowledge of the violation of the ordinance may report the same to the chief executive of the LGU or any of the designated officers.
 - 1.3 All salt samples, when tested and found negative, shall be sent to BFAD or any CHD for confirmatory analysis.
 - 2. Upon findings of any violation of the Ordinance, the officer concerned shall make a report including all evidences and recommend the filing of appropriate court action to the local chief executive.
 - 3. When the Local Chief Executive approves the recommendation, he shall order the filing of the charges with the appropriate court (note: violations

of ordinance as provided by laws and the rules of court are to be filed with the regular court).

- 4. The officer who made the report shall assist in the prosecution of the case.
- 5. After the filing of the case, regular court proceedings will now apply. (Rules on Summary Procedures).
- 6. Upon the termination of the case, sanctions and penalties will be imposed, if violation of the ordinance was proved.
- 7. The fines collected should be used for the effective enforcement of the ordinance or the ASIN Law.
- SECTION 4. The BFAD Director is hereby authorized to impose an administrative fine to existing salt producers/manufacturers/importers/traders/distributors/ repackers based on the provisions of the ASIN Law which shall be immediately applicable to salt producers/manufacturers/importers/traders including those established or organized after the effectivity of this Implementing Rules and Regulations (IRR). The LGUs are authorized to impose administrative fine to hospitals, food service establishments and salt outlets. The administrative fine shall be in the amount of not less than One Thousand Pesos (P1,000.00) but not more than One Hundred Thousand Pesos (P100,000.00), after notice and hearing for violation of any of the provisions of RA 8172 or its implementing rules and regulations.
 - 4.1 Said administrative fines shall be graduated according to category of producers/manufacturers, traders, distributors and repackers. The bigger the volume the bigger the fines.

In the imposition of the said immediate penalty, the imposable fine of One Thousand Pesos (P1,000.00) to Thirty Thousand Pesos (P30,000.00) shall be considered minimum penalty. Thirty One Thousand Pesos (P31,000.00) to Sixty Thousand Pesos (P60,000.00) as medium penalty, and Sixty One Thousand Pesos (P61,000.00) to One Hundred Thousand Pesos (P100,000.00) as maximum penalty, provided that the maximum fine shall be in addition to the revocation of the offender's License to Operate, and provided further that in all cases where the subject matter of the offense is a prohibited product, the BFAD Director shall order the recall and/or withdrawal of the product from the market. **SECTION 5.** The minimum penalty shall be imposed when the violator has:

A good history or record of satisfactory compliance with the rules and regulations prior to the commission of the offense, or absence of previous violation of RA 8172 or its IRR; and

- **SECTION 6.** When the act or omission in violation of ASIN Law and 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 License to Operate shall be imposed.
- SECTION 7. The medium penalty shall be imposed when the offense committed is not attended by any of the circumstances described in Sections 2 and 3 hereof.
- **SECTION 8.** BFAD Director may delegate the conduct of administrative investigation of any violation of the ASIN Law or its IRR to the head of the LGU, provided that the recommendation shall be subject to review and confirmation by BFAD Director before the same shall be deemed final and executory. In such cases, the LGU may be authorized by BFAD Director to collect the fine that may be imposed provided that such fine collected shall be held in trust for the exclusive use by the investigating LGU in the implementation of this Act.
- **SECTION 9.** The second violation of the ASIN Law and the IRR shall entitle BFAD Director to impose the next higher penalty, provided that after third violation BFAD Director shall, in addition to the imposition of the maximum fine, cancel the License to Operate and the Product of Registration of the product involved in the violation, provided further that the persons involved in the violation shall be barred from applying for another license under another business name.

RULE IX FUNDING

Pursuant to Section 10 of R.A. No. 8172, the agencies and institutions required by Section 6 thereof to support the Salt Iodization Program, shall include in their budgetary allocation the amounts necessary to comply with their support to the Salt Iodization Program.

RULE X SEPARABILITY CLAUSE

If any provision of these Implementing Rules and Regulations is declared null and void, for any reason, the remaining provisions shall not be affected thereby and shall remain valid.

RULE XI EFFECTIVITY

The revised Implementing Rules and Regulations including the amendments shall take effect thirty (30) days after its publication in a newspaper of general circulation.

HON. MANUEL'M. DAYRIT, M.D., M.Sc. Secretary of Health and Member, NNC Governing Board

UIS P. LOPANZO,

Secretary of Agriculture and Chairman, National Nutrition Council

LIOSE D. LIN

Secretary of the Interior and Local Government and Member, NNC Governing Board

HON. EDILBERTO C. DE JESUS Secretary of Education and Member, NNC Governing Board

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HON. ELISEA C. GOLUN Secretary of Department of Environment and Natural Resources

MR. FEDERICO & LAXA

Orector of Technology & Livelihood Resource Center (TLRC) HON/ESTRELLA F. ALABASTRO, Secretary of Science and Technology and Member, NNC Governing Beard

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HON. ROMULO L. NERI Secretary of National Economic and Devt. Authority and

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HON. EMILIA T. BONCODIN Secretary of Budget and Management and Member, NNC Governing Board

HON. REPATO S. VELASCO, Ph.D Director General of Philippine Information Agency (PIA)

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MR. RUBEN M. CONTI

Chairman of Cooperative Development Authority

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COLUNNY KHONG HUN Co-Chair, Syb-Committee on Salt Iodization Salinas Foods, Inc. Facilic Farms, Inc. EU Soldteantia MS. ELISA VALDECANTOS Member, NNC Governing Board

Maw MŠ. ČARMELA C. TIANGCO

GMA Foundation Member, NNC Governing Board

DR. JOSE T. SANCHEZ

President, Phil. Medical Association Member, Salt Iodization Advisory Board

WITNESSES:

ADELISA C. RAMOS, MPH, MPA, CESO IV Deputy Director for Food, Bureau of Food and Drugs Department of Health

ndaran

ELSA M. BAYANI, CESO III Executive Director National Nutrition Council

PROF. LETICIA BARBARA B. GUTIERREZ, MSc.

Director IV, Bureau of Food and Drugs

CHECKLIST OF REQUIREMENTS FOR IODIZED SALT IMPORTERS/DISTRIBUTORS

REGULATION DIVISION I:

I. DOCUMENTARY REQUIREMENTS

- 1. Accomplished Petition Form (duly notarized)
- 2. ID Picture of owner/general manager
- 3. If corporation, copy of SEC Registration & Articles of Incorporation
- 4. If single proprietor, copy of Bureau of Domestic Trade Registration
- 5. Copy of warehouse address (with location map)
- 6. Contract of Lease of Office and Warehouse (if not owned by applicant)
- 7. Document indicating terms of agreement between manufacturer/suppliers and importers (duly notarized)
- 8. Document including terms of agreement between importer and local distributor, if importer is not the local distributor (duly notarized
 - 9. Product specifications from manufacturer
 - 10. Certificate of analysis from government of accredited laboratory from the country of origin.

II. TECHNICAL REQUIREMENTS (two copies)

Importers/distributors must have the capability to assure quality of the iodized salt during storage and prior to distribution, which at a minimum shall cover the following:

- 1. Proper storage conditions
- 2. Random testing of stocks of iodized salt prior to distribution (products may be tested in designated government or private analytical laboratories)
- 3. Maintenance of records of quality assurance activities & distribution practices.
- 4. Compliance with packaging and labeling requirements

Annex 1

REQUIREMENTS FOR LICENSING OF IODIZED SALT MANUFACTURER/REPACKER

REGULATION DIVISION II:

Annex 2

I. DOCUMENTARY REQUIREMENTS

Accomplished Petition Form duly notarized.

- ID Picture of Owner/Gen. Manager
- Registration with SEC and Article of Inc. (Xerox) if Corporation/Partnership
- Registration with Bureau of Trade Regulation and Consumer Protection (Xerox) if single and branches
- Location plan/site (Plant Address)
- _____ Notarized Contract of lease of building and warehouse (if not owned by the applicant)
- List of products to be processed/repacked/imported/exported
- _____ Floor plan of working area with complete dimension in meters

II. TECHNICAL REQUIREMENTS (two copies)

- ____ Qualification of key personnel in production and quality control
- Flow chart of manufacturing process with emphasis on identification of critical control points
- Quality Assurance System (QAS) including in-plant quality control
- Certificate of analysis of finished product in accordance with prescribed standard for iodized salt

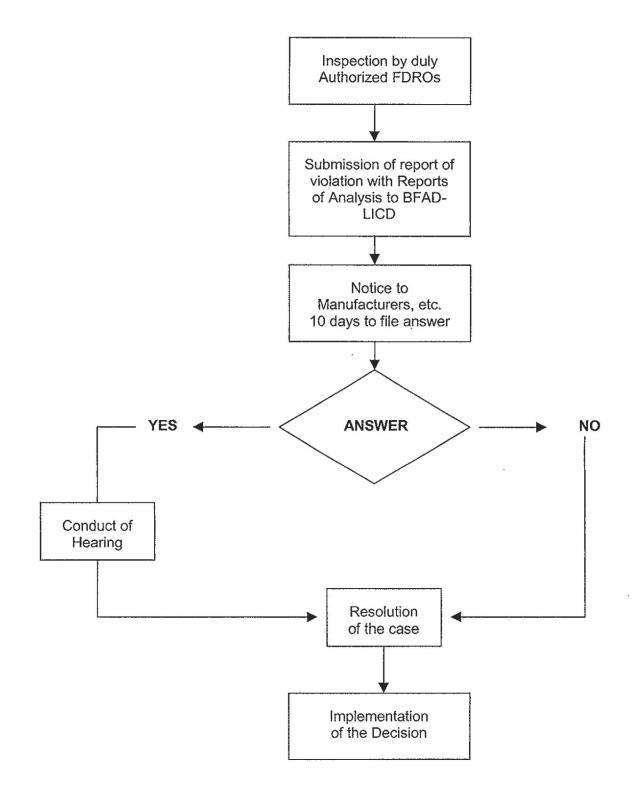
III. OTHER REQUIREMENTS (Product Information)

Two (2) copies of the following:

- ____ Facsimile of the proposed label
- Technical specification of finished products

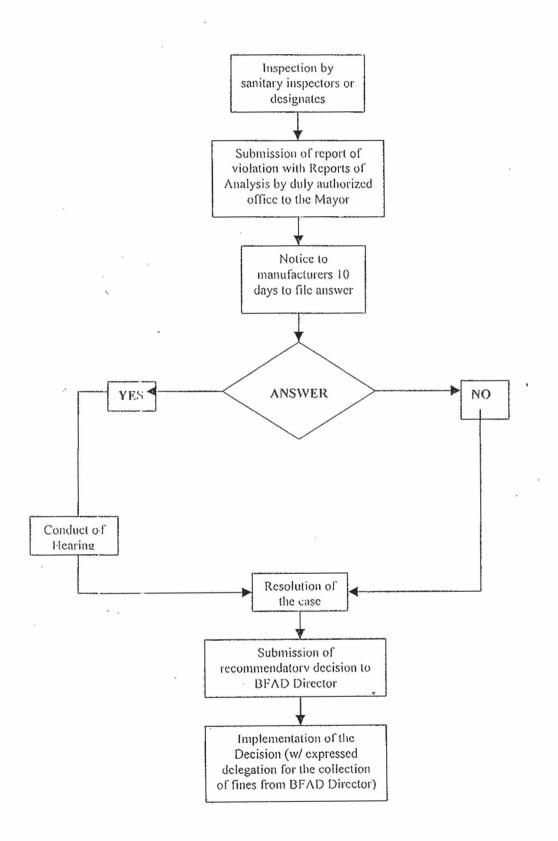
Annex 3

Flowchart of BFAD Administrative Proceedings



Annex 4

Flowchart of LGU Administrative Proceedings (Without Local Ordinances & With MOA)



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Flowchart of LGU Administrative Proceedings (With Ordinances)

