




16 October 2013

FDA MEMORANDUM CIRCULAR

No. 2013-042

To : Manufacturers, Importers, Wholesalers, Repackers and Distributors of Iodized Salt, and Other Concerned Parties


From : KENNETH Y. HARTIGAN-GO, MD
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Subject : Guidelines For Salt Manufacturers, Importers, Wholesalers, Repackers and Distributors To Ensure Adequate Iodization Of Iodized Salt, And For Other Purposes

I. Background and Rationale

Iodine Deficiency Disorder (IDD) is a serious public health threat that leads to serious mental development disorders in young children, from cretinism to more subtle degrees of impaired cognitive development. Its serious consequence results to poor school performance and reduced work capacity in several millions of children.

A National Nutrition Survey (NNS) on goiter incidence rate indicated IDD as a major public health problem in the Philippines. The percentage of households consuming iodized salt was estimated to be between 15-25% for the years 1993-2002. But the estimate rose to 56% in 2003 as shown by the results of the 6th NNS that was conducted by the Food and Nutrition Research Institute-Department of Science and Technology (FNRI-DOST). The significant increase in the number of household using iodized sale was mainly attributed to the DOH “Patak sa Asin” Program.

Subsequent surveys conducted by the FNRI until 2005 revealed a significant decrease in the incidence of IDD. The median Urinary Iodine Excretion (UIE) levels among children aged 6 to 12 years old as well as pregnant and lactating women showed 201 mcg/L, 142 mcg/L, and 111 mcg/L, respectively. The percentage of households using iodized salt rose to 75.4%. Proportion of household consuming adequately iodized salt containing 15 to 40 ppm also rose to 44.5% in 2005. In 2008, however, the NNS revealed that 19.7 % of Filipino children aged 6 to 12 years old still have median UIE level that is slightly below 20 %, and this level, according to the World Health Organization (WHO), indicated a public health problem.

The persistence of IDD condition is alarming despite the implementation of Republic Act No. 8172, otherwise known as “An Act Promoting Salt Iodization Nationwide and for Related Purposes” or commonly known as the “ASIN Law.” The said law required that all



salt for human and animal consumption be iodized in accordance with the specifications as to form, fortificant, method, and composition as determined by the Food and Drug Administration (FDA) The DOH-National Center for Disease Prevention and Control, National Nutrition Council and DOH-National Center for Health Promotion addressed the IDD problem through health programs and promotional activities.

The basic process of salt iodization includes a number of steps to ensure consistent quality during production (Sullivan et al (1995) and stability of the iodine in salt during storage. Salt may be iodized with potassium iodate (KIO₃) or spray mixing if salt is in crystal form. Thorough mixing of the salt after addition of potassium iodate ensures homogeneity. The stability of iodine is influenced by moisture content, purity of the salt, quality, type and amount of fortificant, type of packaging, and storage conditions. The FDA issued FDA Circular No. 2013-007, Amendment of Bureau Circular No. 2007-009 on the Standard Iodine Level of Salts for Strict Compliance of Iodized Salt Manufacturers or Processors, to make sure that adequately iodized salt is available at the household level.

Salt as a food which can be directly used with other foods or added in dishes in very small quantity just to enhance taste and/or as source of iodine. The major contaminants found in salts are usually filth, such as presence of organic and inorganic debris and refuse. Salt as chemical compound is a stable food additive and does not react when it comes into contact with other substances or when exposed to air or other environmental chemicals or contaminants. A local study in several salt establishments showed that the microbiological load of salt was found acceptable based on the FDA standard since salt does not support the growth of microorganisms, including known human and animal pathogens. A local study was also conducted which showed that the level of iodine in iodized salt that was packed in 50 kg polypropylene sacks, with or without a low density polyethylene lining, was fairly stable. However, the level of iodine was higher in salt that was stored with polyethylene lining regardless of warehousing condition or production site. Studies have also shown that the lead content of samples conforms with the FDA standard, while the Ca and Mg contents were found to be within the CODEX standard.

This Circular is being issued to provide guidelines on salt iodization for salt manufacturers, importers, wholesalers, repackers and distributors in order to ensure that all supplies of salt in the country that are offered for sale or for use by consumers are iodized. Moreover, this Circular shall guide the food inspectors in implementing both the quality and safety of salt iodization using hazard analysis and risk-based inspection.

II. Scope and Coverage

This Circular covers all salt manufacturers, importers, wholesalers, repackers, and distributors, which shall ensure that all iodized salt for use and consumption are iodized.

III. Objectives:

The general objective in issuing this Circular is to ensure that only adequately iodized salt is made available to consumers as prescribed by the ASIN Law and consistent with FDA



Circular No. 2013-007. Specifically, this Circular provides for the general guidelines in compliance with the ASIN Law and its IRR, for the purpose of the following:

1. To ensure that all salt produced, imported, sold, offered for sale or use by FDA-licensed salt establishments are consistently iodized to a level based on the provision of FDA Circular No. 2013-007 that requires 30-70 ppm (mg/Kg) iodine content in salt to ensure that at least 15 ppm level of iodized salt at the household level is met;
2. To ensure that all establishments engaged in the salt manufacture, distribution, wholesale, repacking, and importation have FDA License to Operate, which is the basis for determining if the establishment can produce or supply iodized salt in accordance with the standard adopted by FDA; and ensure that all iodized salt products have CPR; and
3. To provide food inspectors general guidelines for inspecting primary producers, repackers and other salt establishments of the salt industry to determine compliance with the ASIN Law.

IV. Definition of Terms

For clarity, the following terms are defined:

1. **Risk-based preventive control measures** includes acceptable preventive control measures, process and sanitation controls, within the facilities or establishment that will be able to address identified hazards and risks and implemented to provide assurances that identified hazards are reasonably prevented or minimized. They encompass a wide-range of control measures specifically designed to protect consumer health, such as prevention of contamination through proper use of equipment and tools, demonstration of training or knowledge on sanitation and hygiene practices, prevention of entry of vehicles of contamination or source of contamination, like animals.
2. **Authorization** as defined by RA No. 9711, means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.
3. **Hazard** is a significant biological, chemical, or physical threat to health or that can reasonably or likely to cause harm to health if not controlled.
4. **Hazard analysis** is the process of collecting and evaluating information on hazards associated with the food under consideration, such as food additive, iodized salt, to decide which are significant and must be addressed by risk-based preventive control measures by the establishment and risk-based inspection by the FDA.



V. Guidelines

The following are the guidelines to ensure compliance with this Circular:

1. All establishments engaged in salt manufacture, importation, wholesale, repacking, and distribution shall secure a License to Operate from the FDA, which shall be issued only to establishments that have demonstrated capacity to produce, supply and ensure iodized salts. Salt products shall be iodized at 30 to 70 ppm of iodine (mg of KIO_3 /Kg of salt).
2. The Philippine salt industry has been in existence for several years and the method of production has practically remained unchanged. However, pursuant to FDA mandate, minimal regulatory measures to ensure both safety and quality of salt have to be set in place. All establishments shall ensure the following as appropriate to their operations:
 - 2.1. Provision of proper containment or housing to prevent gross contamination. Salt production facilities shall have durable roofing. Alternative roofing or covering, such as tarpaulin preferably with polyethylene plastic lining. Salt production facilities shall have adequate walling, particularly in areas where the preparation of fortificant takes place and where iodized salt products should be protected from hazards. Cemented flooring is highly advised. *Sawali* as an alternative to cemented flooring may be permitted, provided there is at least 5 cm buffer of salt on top of a *sawali*. *Sawali* should be in good condition. Damaged or worn-out ones should be replaced immediately.
 - 2.2. Potable water for brine solution shall be used for salt cooking. Salt premises shall be free from pets, animals, and rodents.
 - 2.3. Provision of appropriate equipment, tools and other farm implements that are maintained and kept clean periodically.
 - 2.4. Provision of training on sanitation and hygienic practice for handlers given by the food industry or food industry association, academe, or national and local government unit.
3. All facilities for iodized salt production shall be free from contaminants, such as manure, debris, filth, foreign materials, litters or waste and refuse.
4. FDA officers and inspectors shall be allowed access to salt establishments and facilities during office hours for inspection to ensure compliance with the provisions of this Circular. The food inspectors shall focus on ensuring that salts are consistently iodized or all salts are iodized when they leave the salt establishment for distribution, sale or use. Further, the food inspectors shall inspect salt establishments, farms or seabed, holding area, iodization area and other facilities following hazard analysis and risk-based inspection, as defined in this Circular, to ensure risk preventive control measures are in place and implemented. The food inspectors shall:



- 4.2. Check if the iodine fortificant (KIO₃) is added at 30 to 70 ppm (mg/Kg). Verification or validation shall be made by FDA inspectors through interview of production personnel and review of records. The FDA inspectors should take note that the result of analysis could be a good indicator of adequacy of iodine content, especially when samples are taken from actual production and inventory, and from testing of retention samples. Record of salt testing written in a logbook, computer-based records or similar media shall be kept for reference of the FDA inspectors.
- 4.3. Check if control measures are implemented against gross filth contamination of salt and iodized salt are implemented;
- 4.4. Check if food contact surface, such as *sawali*, packaging materials, containment or housing are appropriate to prevent gross contamination; and
- 4.5. Verify or validate documents and records, as appropriate to the operations, that will show enforcement of hygiene and sanitation, supplier of salt or source of salt, iodized salt production record, volume of fortificant purchased, proof of iodization or test report on iodine level of salt, and distribution records, among others.

VI. Repealing and Separability Clause

Rules, regulations, and other related issuances inconsistent with or contrary to this Circular are hereby repealed, amended, or modified accordingly. All other provisions of existing issuances which are not affected by this Circular shall remain valid and in effect.

In the event that any provision or part of this Circular is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

VII. Effectivity

This Memorandum Circular shall take effect immediately.