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## **General Guidelines for Drafting a Legal Framework**

### **Mandatory Iodization and Fluoridation of Salt for Human Consumption**



**Division of Health Systems and Services Development**  
**Regional Program on Oral Health**  
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## GENERAL GUIDELINES FOR DRAFTING A LEGAL FRAMEWORK

### *Mandatory Iodization and Fluoridation of Salt for Human Consumption*

#### GENERAL CONSIDERATIONS

As a first point, the following are listed: the background and current laws, decrees, and general regulations in the country on the fluoridation and iodization of salt.

#### *Whereas:*

- I. Iodine and fluorine deficiencies are serious health problems in the country, due to their impact on health and the economy;
- II. Their rising incidence has led to a significant deterioration in health status, principally among the disadvantaged population;
- III. One of the most effective preventive measures against IDD and caries is to fortify salt for human consumption with iodine and fluorine;
- IV. The success achieved in the eradication of endemic goiter in each country through mass consumption of iodized salt indicates that salt would be also an appropriate vehicle for the intake of fluorine.

The following is decreed:

### UNIFIED REGULATIONS OF THE LAW ON MANDATORY IODIZATION OF SALT FOR HUMAN CONSUMPTION AND THE NATIONAL FLUORIDATION PROGRAM

#### CHAPTER I

#### DEFINITIONS

- Art 1. "Salt for human consumption with no other additive" is the term used for the commercially pure or purified product chemically identified as sodium chloride, extracted from natural sources. Occurring in the form of colorless crystals, it is water-soluble and has a clearly salty taste; its consumption is authorized by the Health Authority. Excluded from this definition is salt utilized for non-dietary industrial purposes.
- Art 2. Depending on its use, salt consumed directly or indirectly is considered salt for human consumption.
- Art 3. "Salt for direct human consumption" is understood as salt used in the kitchen and at the table for the preparation and seasoning of food.
- Art 4. "Salt for indirect human consumption" is understood as salt used in the food industry as a preservative and seasoning, and, in general, as an additive in food processing.

Art 5. "Salt for animal consumption" is the term used for the product made of sodium chloride utilized only in animal feed.

## CHAPTER II

### GENERAL SANITARY REGULATIONS

Art 6. The periodic monitoring of salt for human consumption is reserved to the Ministry of Public Health through the corresponding Department.

Art 7. All salt produced in the country for direct human consumption--that is, table salt and kitchen salt--must be iodized or iodized and fluoridated prior to sale.

Art 8. Salt for human consumption, listed by the characteristics, purity, and granulation indicated in these Regulations, is divided into three groups:

- Ground salt
- Refined salt
- Table salt

Art 9. Salt for human consumption must be in the form of cubical white crystals, bonded together to form small pyramids with a quadrangular base.

The various types of granulated salt must be uniform within each type, and, moreover, must be free of nitrites, impurities, and microorganisms that would indicate improper handling of the product--that is, coliforms and other pathogenic or chromogenic microorganisms should not be present. The banal germ count may not be higher than 20,000.

Art 10. Ground retinated salt is the product of processes to eliminate hygroscopic magnesium and calcium salts, organic impurities, sand, and shell fragments; crystals must go through a strainer made of No. 20 mesh, and at least 25% must go through a strainer made of No. 60 mesh. Moreover, the physicochemical properties of the salt should adhere to the criteria established in NTN-INEN standard 57 and the following parameters:

- Moisture at 150°C: no greater than 2%
- Insoluble residue in water: no greater than 0.3%
- Sodium chloride (based on dry product extracted from the anticaking agent): no less than 98%
- Degree of turbidity: no greater than 25%

Art 11. Table salt has the same granulation and physical and chemical constants established for refined salt, except that the moisture content should not exceed 0.5%; this limit requires the addition of anticaking agents at a level not to exceed 2%, a proportion that will permit the percentage of sodium chloride to fall to 96%.

Art 12. Salt for direct human consumption should be iodized or iodized and fluoridated, meeting the specifications and sanitary standards corresponding to each type described in this Chapter, and should contain:

- Iodized Salt, a product consisting basically of sodium chloride (NaCl), fortified with potassium or sodium iodine (KIO or NaIO respectively), or potassium iodine (KI) within the limits of free iodine in a concentration of 75mg per kg of salt, permitting a tolerance of 25 mg per kg of salt, more or less.
- These concentrations may be modified by the Ministry of Health, in response to the findings of the respective nutritional surveys and when justified by epidemiological studies on iodine dosage.

Art 13. To add iodine, only potassium iodine or sodium iodine and potassium iodine should be used.

To add fluorine, only sodium fluoride or potassium fluoride (NaF or KF, respectively) should be used, depending on the method of production (dry or wet method).

Art 14. Salt for human consumption destined for industries other than the food industry is exempt from fluoridation.

Art 15. Salt for human consumption must be packed in new containers that preserve the integrity of the product, conferring adequate protection against contamination and moisture. Packaging material in contact with the product must be resistant to its action, and of a nature that does not alter the composition or organoleptic properties of the product.

Art 16. Establishments and facilities involved in the industrial production of salt for human consumption must, in addition, adhere to the general standards in the Sanitary Code and the present Regulations.

Art 17. The production and fractionation of iodized salt for indirect use may take place only in facilities that have received prior authorization from the Health Authority.

Art 18. Individuals or legal entities that own the facilities in Art. 17. must adhere to the standards in the Sanitary Code.

Art 19. Centers for the production, fractionation, packaging, or repackaging of iodized salt and fluoridated iodized salt or salt for indirect human consumption must, in addition, adhere to the technical standards of the Sanitary Code under the section on environmental sanitation and equipment.

Art 20. In order to guarantee the correct addition and persistence of iodine and fluorine in the salt, the producer must use an efficient, economically feasible process, utilizing the spray method, which guarantees homogeneous distribution of the elements in such a way that a random sample assayed possesses the iodine and fluorine content established in the present Regulations.

Art 21. Imported salt for marketed in the country for direct or indirect human consumption must meet the specifications contained in the Law regarding physical, chemical, and microbiological properties and micronutrient additives (iodide or iodate and fluoride).

Art 22. The equipment in plants for refining and purifying salt for human consumption must be made of stainless steel, given the high corrosiveness of this raw material.

The plant must have:

- a) A drum dryer that produces a continuous flow of salt, purifying it and raising its temperature to 120° C throughout.
- b) A turbine and centrifuge system that absorbs the impurities extracted from the product in its passage through the drum dryer by means of a strong current of air.
- c) Strainers made of stainless steel mesh so as not to contaminate the product with rust.
- d) Mechanized transport from one stage of the process to another, with no worker having contact with the product.
- e) Precision mixer, given the low dose of potassium iodate and sodium fluoride or potassium fluoride to be added. This equipment consists of vertical cone-shaped mixers with high-precision epicycloidal motion; they consist basically of a conical receptacle containing an Archimedes screw to homogenize the mixture required by the Ministry of Public Health.
- f) Fully automated packaging plants for salt for human consumption in which the full cycle can run its course without human hands touching the product once it has been retinated.

The equipment described above is the minimum required for these processes. Quality control of the addition of iodine and fluorine shall be exercised with each batch of the mixer; two samples shall be collected that must be analyzed and labeled with the date and batch number, and this information must be available to the Ministry of Public Health for 45 days. Salt refineries and purification plants, as well as the facilities where salt for human consumption is packaged, must be licensed by the Ministry of Public Health.

### **CHAPTER III**

#### **PACKAGING AND LABELING**

Art 23. The packaging of iodized and fluoridated iodized salt for direct consumption must take place under the conditions stipulated in Art. 16 of these Regulations.

Art 24. Containers for the sale of iodized and fluoridated iodized salt must have a visible label in Spanish, with clear lettering, and, in addition to the name and patent number, if any, provide the following information:

- 1) The designation "fluoridated iodized salt" or "iodized salt" for human consumption.
- 2) The net content of product in the container, expressed in decimal units.
- 3) The name and address of the manufacturer and Sanitary Registration number, with the patent and lot number.
- 4) The legend "Manufactured in its country of origin"

- 5) Statement of the additives used.
- 6) Warning for fluoridated iodized salt: "Do not consume or sell this product in areas where water for human consumption has fluorine levels higher than 0.7 ppm."

Art 25. Containers for salt for indirect consumption must have a visible label in Spanish that provides the following information:

1. The designation "salt for use in the food industry."
2. Net contents expressed in metric units.
3. Name and address of the manufacturer.
4. Registration number.
5. Patent number.

## **CHAPTER IV**

### **MONITORING AND SANCTIONS**

Art 26. The Ministry of Public Health, through its technical departments, shall keep records on the industries that produce salt for human consumption. These records shall indicate technical aspects such as the volume produced, the types of products produced, salt distributors, and other data necessary for maintaining an efficient monitoring system.

Art 27. The individuals, corporations, commercial enterprises, etc. listed as the owners of plants or facilities that process, fractionate, package, or repack iodized salt for the food industry and salt and fluoridated iodized salt for human consumption will be the parties directly responsible for all products sold with defective processing or deficient packaging. No excuses aimed at diminishing or evading this responsibility shall be accepted.

Art 28. Centers where iodized salt and fluoridated iodized salt are sold, such as supermarkets, warehouses, grocery stores, etc., that do not comply with the provisions of the present Regulations, shall be sanctioned with the penalties established in the Sanitary Code.

Art 29. Every salt iodization and fluoridation plant must maintain quality control records for the production process. These records must be available to health or trade authorities upon request.

Art 30. Salt for purposes other than the food industry and that is not considered suitable for human consumption is exempt from the above requirements

Art 31. Facilities that produce salt for direct or indirect human consumption must adhere to the sanitary and hygiene standards established in the Sanitary Code and these Regulations.

- Art 32. The possession of common non-iodized or fluoridated salt is permitted only to the concession-holders of deposits in production, the industries that refine or iodize and fluoridate salt, and those that utilize it for non-dietary industrial purposes.
- Art 33. The sale of domestic or imported salt for direct or indirect consumption that does not meet the requirements in the preceding articles shall be considered a crime against public health, and the parties responsible shall be sanctioned, as provided for in the Penal Code.
- Art 34. The General Health Directorate of each country shall enforce all provisions on hygiene, quality, iodine and fluorine content, and packaging of salt for direct and indirect human consumption, salt for use in the food industry, and salt for animal consumption contained in the present Regulations.
- Art 35. Producers of iodized and fluoridated iodized salt for direct human consumption, salt for the food industry, and salt for animal consumption, and refineries and plants that package or repackage, sell, or distribute salt that do not comply with the provisions of the present Regulations shall be sanctioned with the penalties established in the Sanitary Code.
- Art 36. When a violation of the regulations on quality, iodization, or fluoridation has been verified, the producer or dealer shall be sanctioned according to the provisions in the Sanitary Code.
- Art 37. The potentiometer, containing a **specific electrode with a fluoride gauge**, is used to verify compliance with the chemical specifications for fluorine established in these Regulations.
- Art 38. The manufacturers of containers for fluoridated iodized salt may produce them only for individuals or companies whose Sanitary Registration is current and must send the Salt Fluoridation Program a monthly list of the containers made for salt.

## **TEMPORARY PROVISIONS**

The necessary temporary provisions are listed.

### ***Recommendations***

- Tariff barriers should not be considered the basic criteria for these sanitary regulations.
- Social policies and sanitary criteria should prevail over business and/or trade criteria. NAFTA, MERCOSUR, C. E. E.
- The countries should evaluate the existing legal framework to support the iodization programs.
- This will require a review of the laws, decrees, and regulations so that programs can be implemented effectively.
- The mandatory introduction of iodized and fluoridated iodized salt (add fluorine where necessary) in the Food Code.
- The regulations on the additional use of fluoride should be reviewed to reduce the risk of exposing the population to fluorosis.

- Strict monitoring of the salt industry should be established.
  - Quantitative and qualitative
  
- The public sector should exercise strict control.
  - Epidemiological surveillance.
  - Quality assurance.
  - A commitment should be obtained.
  - Foreign trade (imports and exports).
  
- Support for the programs should be ensured.

As a recommendation, the following table lists the countries that need to strengthen, modify, or draft legislation in this area.

STRENGTHEN	MODIFY			DRAFT
		<i>Iodine</i>	<i>Fluorine</i>	
Colombia	Dominican Rep.	No	Yes	Caribbean (12 countries) Haiti Guyana Belize
Chile	Panama	No	Yes	
Brazil	Nicaragua	No	Yes	
Bolivia	Honduras		Yes	
Argentina	El Salvador		Yes	
Ecuador	Guatemala		Yes	
Mexico	Cuba		Yes	
Venezuela	Costa Rica		Yes	
Canada				
Jamaica				
Paraguay				
Peru				
Uruguay				