RWANDA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR FORTIFICATION OF EDIBLE SALT

OCTOBER, 2019

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ABBREVIATIONS

1.	FAO	-	Food and Agriculture Organization
2.	GMP	-	Good ManufActuring PrActices
3.	HACCP	-	Hazard Analysis Critical Control Points
4.	Rwanda FDA	-	Rwanda Food and Drugs Authority
5.	WHO	-	World Health Organization

ACKNOWLEDGEMENTS

FOREWORD

RWANDA FDA is a regulatory body which is mandated among other things, to protect consumers against health hazards associated with food.

One of the means for achieving this goal is subjecting processedfood to evaluation to ascertain their compliance with set standards of quality and safety prior to authorizing their sale in Rwanda. Processed food that passes the pre-market evaluation is registered and registration certificate issued as evidence that it may be allowed for sale inRwanda.

It is our hope that applicants will find the document easier to follow and be encouraged to apply for registration of the their products, so as to comply with provisions of the **Act N° 003/2018 of 09/02/2018** and relevant regulations.

It is expected that evaluation for safety of food products will not only be thoroughly but also faster so effectively protecting consumers and at the same time promoting business and the national economy as a whole.

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DIRECTOR GENERAL

INTRODUCTION

Rwanda FDA has made food fortification mandatory for salt. The regulation No……..governing fortification of food in Rwanda gives a legal framework for the effective and efficient fortification of salt, wheat flour, Milled Wheat (Corn) Products , edible oil and fats and sugar in Rwanda.
The present guidelines have been developed for use by those who may wish to engage in the importation or manufacture of edible salt for sale in Rwanda. These products shall be fortified using **Potassium Iodate** which is the most stable form.

The guidelines comprise 6 chapters.

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1.1 DEFINITIONS OF TERMS

For the purposes of these guidelines, the following definitions shall apply:

Law

Law Nº 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and Law Nº 47/2012 of 14/01/2013 relating to the regulations and inspection of food and pharmaceutical products.

Applicant

Means a person or company who may submit, to the Authority, application for registration of processed food;

Authority

Means the Rwanda Food and Drugs Authority or the acronym "Rwanda FDA" established by Article 2 of the Law Nº 003/2018 of 09/02/2018.

Brand name

Means a trade name for the food;

Codex

Means the Codex Alimentarius Commission responsible for execution of the joint FAO or WHO food standards programme;

Competent Authority

Means institution responsible for food safety control recognized by the government of the country of origin or country of supplier;

Common name

Means any name by which a food is commonly known in the country of origin or name established in a standard recognised by the Authority;

Country of origin

Means the country in which the processed food was manufactured or produced or from which the food was re-packaged;

Container

Means a bottle, jar, box, packet, sachet, or other receptacle which contains and has direct contact with food, and where any such receptacle is or is to be contained in another receptacle;

Director General

Means the Chief Executive of The Rwanda Food and Drugs Authority appointed under Article 7 of the Law;

Food

Means any article other than drugs, cosmetics and tobacco used as food or drink for human consumption and includes any substance used in the manufacture or treatment of food;

Food additive

Means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufActure, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the charActeristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.

Food product registration

Means official recognition or approval by the Authority for food to be sold for human consumption in the country.

Food registration certificate

Means a certificate issued by the Authority as evidence that the food has been registered by the Authority.

Food/dietary supplement

Means a product other than tobacco, cosmetics or drugs intended to supplement the diet, and shall include all of the following characteristics:-

a) Contains concentrated source of one or combination of the following:
   i. Vitamins;
   ii. Minerals;

iii. Amino acids,
iv. Essential fatty acids;
v. Enzymes and other Metabolites
vi. Pre and/or probiotic
vii. Natural substances of plant or animal origin with nutritional or physiological function;

b) Intends to be taken orally in the form of tablet, capsule, powder, soft gel, gel cap, pellet, pill, granules or liquid.
c) It is not presented for use as a convectional food or as a substitute of a meal or the diet.
d) Labelled and marketed as a food / dietary supplement

e) Does not suggests in any way that the product is meant to diagnose, treat, cure or prevent a disease, disorder, abnormal physical or mental state or a particular physiological function.

Good Manufacturing Practices or the acronym GMP

Means measures or practices undertaken to ensure that the food produced, manufactured or processed is of good quality and safe for human consumption.

Hazards Analysis Critical Control Points or the acronym HACCP

Means a system, which identifies, evaluates and controls hazards which are significant for food safety along the food chain.

Export Permit

Means a permit or warranty issued by competent authority in the country of origin showing that the food is fit for human consumption and that it meets the standards prescribed by the competent authority of that country, stating such standard.

High risk food for general purpose

Means food classified as such by the Authority because of its high possibility of being contaminated or have intrinsic properties which can support the growth of pathogenic micro-organisms or contains chemical toxicants.

High risk food for special nutritional purpose

Means high risk food classified as such by the Authority because of its intended use, as food for special nutritional purpose, including food supplement or infant formulae, which is for a vulnerable group who, due to their physiological conditions, are susceptible to adverse health effects when they consume unsafe foods

Ingredient

Means any substance, including a food additive and excluding processing aid, used in the manufacture of food;

Label

Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any food;

Low risk food

Means food classified as such by the Authority because of its relatively lower possibility of being contaminated with pathogenic micro-organisms or other chemical toxins compared to the high risk food;

Manufacture

Means all operations involved in the production of food from one or more ingredients and includes, preparation, processing, filing, transforming, packaging, and repackaging and labelling of food;

Manufacturer

Means a person or company that is engaged in the manufacture of food;

National standard
Means a Standard *gazetted* under the Rwanda official gazette

Non -registrable foods

Foods that are exempted from the registration process and this includes but not limited to, agricultural/farm food produce such as cereals, pulses, roots and tubers, fruits, vegetables, nuts and oil seeds, spices, raw meat and fish, eggs, raw milk, which is used as raw materials or for direct human consumption and all perishable food as prescribed in these Guidelines and Registration of Foods Regulations;

Packaging material

Means any material meant for wrapping, enclosing and protecting food substances for sale, distribution, storage or use, including caps, corks, leads, crown, food contact surfaces and covering or coating materials which do not

form part of the food and are not intended to be consumed together with such food;

Perishable Food

Means food that has a shelf life, not exceeding 30 days when kept at ambient temperatures. Typically, such foods require cold chain storage to extend shelf life;

Processed food

Means food that is processed to extend its shelf life, packaged, labelled, and complying with specified standards ready to offer to the consumer.

Qualified Person

Means a person who is a holder of at least a diploma in food science, food technology or Nutrition or related sciences from a recognized institution and entrusted with the responsibility of ensuring that each batch/lot of the finished product aspired for registration is manufactured in accordance with Good Manufacturing Practices to meet standards prescribed in respect to that food.

Registrant

A person or company whose food product is registered by the Authority.

CHAPTER 1

PROCESSING PREMISES- GENERAL REQUIREMENTS

In general, it is the responsibility of the manufacturer of edible salt to apply for licensing of premises to Rwanda FDA. Importers/ agents of manufacturers of these products shall present the premises license from the regulator in the country of origin before being allowed to import.

All products for which applications for registration are presented to Rwanda FDA must conform to safety and quality requirements set under the respective standards and must have been manufactured in accordance with GMP requirements prescribed under the Law.

In addition, local manufacturer (applicant) should register his food manufacturing premises prior to submission of application for registration of the products.

PROCESSING EQUIPMENT

Any fortified edible salt factory shall have an automated line. In addition, there shall be an additional line for fortification including batch/ continuous mixer.

CHAPTER 2 QUALITY ASSURANCE OF THE POTASSIUM IODATE RECEIPT, STORAGE AND DELIVERY

The purpose of the Quality Assurance of the fortificant receipt, storage and delivery are to ensure that the factory always has enough potassium iodate in stock for at least 3 months of production of fortified salt. The iodate compound is stored under adequate conditions and is used based on the "first-in, first-out", as determined by the expiration date.

I. Procedures

1.0 Receipt and Storage (warehouse)

The responsible personnel shall :

1. Every time a new lot of the potassium iodate compound is received in the factory, check that the containers are hermetically sealed and that a Certificate of Analysis (COA) has been included.
2. Record the number of containers/ drums received, lot numbers, date of expiration, and the name of the person who is receiving the delivery.
3. Store the containers in a clean dry area and away from chemical products or other potential contaminants. If possible, store the drums of iodine fortificant in an air conditioned room.
4. Store the containers in such a way that the first received are used first, following the "first-in, first-out" system.

2.0 Delivery (warehouse)

The responsible personnel shall :

1. When container is dispatched to the storage area, record the date of dispatch and name of the person who is receiving the order.
2. Send a copy of the log form every week to the Quality Control Department and the Head Production Manager.

3.0 Confirming content of iodine in the fortificant

1. At least once a week, an employee of the Quality Control Department shall visit the warehouse and the fortification area to ensure that the iodate/iodide compound is being used in the correct order, and that all records are kept up to date. Reviewer must sign on the provided form.

2. At least once a month, take two 25 g samples from each drum of the iodine compound that will be used on the day of sampling. Package them in opaque airtight containers and send them to an external laboratory to confirm the iodine content using the quantitative titration with thiosulphate.
3. When the test result are available report to the Production Manager for inclusion in appropriate form.
4. If the test results are below the claimed content on the Certificate of Analysis, contact the iodine supplier.

II. Records and Reporting

The responsible personnel shall keep updated all the records, which should be periodically reviewed by personnel from the *Quality Control Department*. Weekly reports should be sent to the *Factory Manager* and the Quality Control department, where the reports will be filed, too.

CHAPTER 3 QUALITY ASSURANCE OF THE SALT FORTIFICATION PROCESS

The purpose of Quality Assurance of the salt fortification process is to ensure that:
• The iodine compound is properly diluted either in water or mixed with a dry filler to produce an appropriate premix.
• Equipment for volume determinations and for solution preparations is adequate and weighing equipment is in good order.
• Spraying or feeder equipment is properly serviced to ensure consistent results.
• Ratio salt produced (kg)/iodine fortificant (kg) is close to the theoretical ratio based on quantities used and dilutions effected.

I. Procedures

1.0 Calculating the amount of iodine compound per batch or tonnage of fortified salt (Production Manager)
The amount of potassium iodate compound will depend on process used and dilution factors involved as well as the final concentration according to standards. Some physical parameters relating to the potassium iodate are provided. Iodate is usually used for the dry or wet processes or salt that are not highly refined.
Felistus to clear the confusion btn iodate and iodide

	Solubility g/L			% Iodine in Salt
	20ºC	30ºC	40ºC	
Potassium Iodate	81.3	117	128	59.5
Potassium Iodide	1440	1520	1600	76.5

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a. Dry Mixing, Batch Process

Prepare the premix for dry mixing by mixing potassium iodate with a filler in a ratio of 1:9 (1 part of the iodate salt and 9 parts of the filler). Fillers can be calcium carbonate or the same dry salt. This premix should have an iodine content of about 60 g/kg. Another alternative is to weight 8.4 kilograms of potassium iodate and add sufficient filler up to 100 kilograms. The content of iodine in the second premix
should be 50 g/kg.

b. Drip Feed and Spray Mixing Process

The addition rate of the drip-feed or spraying process depends on the final iodine content and weight of fortified salt flowing per specific period or the weight of fortified salt per batch. In the case of a production of 5 tons (5,000 kilograms) per hour the solution has to contain enough iodine to fortify the salt to the appropriate level.

Use the following equation to determine the spraying rate or the dripping feed rate
Assuming a fortification level of 50 ppm (50 mg/kg), the 5 tons would require 250 g of iodine to be sprayed or drip fed over a period of 1 hour. If the iodine concentration in the premix solution is 50 g/L, the system would have to be set in such a way as to deliver 5 liters of the premix solution per hour, according to the equation above. If more than 5 liters is delivered within an hour the salt would be over-fortified and if the delivery is less than 5 liters the salt would be under-fortified according to a 50 ppm standard.

The concentration of the premix is usually constant, but the flow rates per hour of the salt may vary. Thus, adjustments must be done to the addition of the premix rate. In order to prepare the premix solution, estimations of the amount of the iodine compound must be done. In the case of potassium iodate, a solution of 50 g/L of iodine should require 84 grams (i.e. 50 g / 0.595) per liter, while for potassium iodide the amount is 65 grams (i.e. 50 g / 0.765). The water should be potable and preferable distilled.

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2.0 Preparing Premix (Production Personnel**)**

The production personnel in charge of the preparation of the premix should follow strictly the instructions of the factory manger, and record the work done.. Data should always be ready to show to the Quality Control Department when requested. When a form is completely filled-out, send a copy to the Quality Control department.
On a weekly basis check the performance of the blenders, balance, pump, drier and the integrity of the spraying equipment. Record the results of this activity.

3.0 Records of Production (Production Personnel**)**
The production personnel should also keep up-dated all the information about premix used and amount of salt produced during each shift. Send report to the Quality Control Department at the end of each shift.

4.0 Collecting Samples for Quality Control(Packaging Department)
Collect 500 g of salt every hour, and place inside an opaque 5-kg container. Detect the presence of iodine using a qualitative test (e.g. the Rapid Test Kit) to assure that the iodine premix is being added constantly in the process. When the shift (8-hours) ends, mix well the single samples to prepare a composite sample, and label it with the date, hour and number of batch or batches. Include the amount of salt (in kilograms) produced in the period, as well as the amount of premix that was used. Send sample to the laboratory.

II. Records and Reporting

The Production department shall keep updated and adequately filed records of the calculations done, amounts of salt produced and amounts of fortificant used, as well as description of actions taken during production to keep the fortification process performing as expected. A copy of these records will be sent daily to the Quality Control Department

CHAPTER 4 QUALITY CONTROL OF FORTIFIED SALT

The purpose of Quality Control of the fortified salt is to ensure that:

• All salt samples contain iodine levels > 20 mg/kg (or whatever is the regulatory minimum).
• 80% samples have iodine levels within the factory level (e.g. 30 to 60mg/kg) and the average concentration is close to the addition level at the factory (e.g. 45 mg/kg).
• Fortified salt is packaged and labeled as required in the National Standards for General Labeling of Prepackaged Foods and the Salt Fortification Regulations.
The responsibility for this component is the Quality *Control Department*, which should send daily reports to the *Production Manager*.

Commented [WU3]: See the std

I. Procedures

a.Supervision and sampling
The responsible personnel shall :
1. Make unannounced visits to the storage facility and fortification section to check that the operators are following instructions and the records are being filled out timely. Sign on the provided form to confirm completion of this supervision.

2. Make unannounced visit to the packaging site to verify that the operators are taking 500g of salt every hour, and that they are preparing a composite sample per shift, and labeling as expected.

b. Iodine determination

The responsible laboratory personnel shall:
1.Mix well the composite samples. Determine the iodine concentration using the quantitative titration method.

2. Record test results and express them in terms of milligrams iodine per kilogram of salt.

3. Prepare a **daily** composite sample, mixing 500 g from each of the samples collected on each shift. Mix well. Determine the content of iodine, and record results. Store the remaining daily-composite sample in an air-tight and opaque container. Identify the sample with the date, and include the amount of iodine from quantitative testing. Keep this sample in the sample-store room for up to a month.
4. If abnormalities are found, discuss immediately with the Production Manager the suitable corrective actions.

II. Records and Reporting

The responsible personnel shall:

1. Complete the form with the data provided by the production department.

2. Calculate the ratio salt produced/premix used, expressed in kilograms of salt over kilograms or liters of premix. The ratio should be close to 1,000 if a premix of 50 g/kg (or 50 g/L) was used to produce iodized salt at 50 mg/kg. Factory manager should calculate the adequate figures if the conditions are different.

3. Record all the needed information, and on a daily basis send a copy to the production manager.

4. At least once a month, select randomly two daily-composite samples from the sample store and send a portion of those to an external reference laboratory for the quantitative determination of iodine.

5. Once the report from the external laboratory is received, the records of the test results shall be kept and compared to the ones recorded on that day with the laboratory data, and if discrepancies exist, the factory shall identify the reason, and apply corrective measures that are necessary.

6. Send reports to the production manager about corrective actions or confirmation of the earlier findings and deductions from the work of the Quality Control Department.

CHAPTER 6 REGISTRATION OF FORTIFIED EDIBLE SALT

All fortified Edible Salt products shall be registered by Rwanda FDA as per the provisions of the Regulation No…..for registration of pre packaged foods

PROCESS FOR IMPORTS MONITORING
To make sure every batch is up to std. Felistus to share the report from Zambia

CHAPTER 7 CONSUMER AWARENESSS/ EDUCATION

1.Media Campaigns on Fortification(general public and people with special diets)
2.To link with the local government to spread the information up to the community level(focus on women of reproductive age and breastfeeding mothers- prevalence of goitre)
3.School Outreach(children –impaired cognitive development)