RWANDA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR FORTIFICATION OF SUGAR FOR DOMESTIC CONSUMPTION

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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 maize (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 sugar for sale in Rwanda. These products shall be fortified using **Vitamin A premix stabilized with vitamin D3** .

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 sugar 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 sugar 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 PREMIX RECEIPT, STORAGE AND DELIVERY

The purpose of the Quality Assurance of premix receipt, storage and delivery is to ensure that:

• The factory always has enough vitamin A premix stabilized with vitamin D3 inventory for at least 15 days of production of fortified sugar.

• Premix is stored under adequate conditions and is used based on the "first-in, first-out".

• Premix bags are sealed and labeled, and they contain the minimum retinol level that is claimed.

Those directly responsible for achieving these objectives are the *Warehouse Manager* and the *Head of the Quality Control Department*, who should frequently inform the *Factory Manager* and this, could even be on a daily basis if the production is large.

I. Procedures

a. Receipt and Storage

1. Every time a new lot of vitamin A premix is received in the factory, check that the bags are properly sealed and the label contains the following: manufacturing company, the lot number, date of production, and the vitamin A content.

2. Record the number of bags received, lot numbers, date of production, date of receipt, and the name of the person who is receiving the delivery.

3. Store the premix bags on top of palettes made of a suitable material, in a clean dry area and away from chemical products or other potential contaminants. If possible, store the premix bags in an air conditioned room.

II.DELIVERY (WAREHOUSE)

1. When premix is dispatched for sugar fortification, 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 Production Manager.

c. Confirming content of vitamin A in the premix (Quality Control Department**)**
1. Once in a while, an employee of the Quality Control Department visits the warehouse and the fortification site to ensure that premix is being used in the order of delivery, and that records are being kept up to date. Supervisor must sign in the provided form.
2. it is recommended that at least once a month, take two 50 g samples from a lot of premix received**.** Package them in an opaque airtight container and send them to an external laboratory to confirm the vitamin A content.
3. Record the analytical results completed by the warehouse department.
4. If the results do not meet the premix specifications, contact the vitamin A premix supplier.

III. 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 SUGAR FORTIFICATION PROCESS

Check the EAC STD FOR THE LEVELS OF VIT A IN FORTIFIED SUGAR

The purpose of Quality Assurance of the sugar fortification process is to ensure that:

• Premix is free flowing and adequately added to the unfortified sugar using an auatomated feeder equipment.

• Feeder is dispensing premix adequately as verified by the amount of premix discharged in relation to the sugar flow.

• Ratio sugar produced (MT)/premix used (kg) is close to 2.0 (or 1,000 if ratio is expressed in terms of 50 kg-bags of fortified sugar per 25-kg bags of premix).

I. Procedures

a.Beginning of the shift

The responsible personnel shall:

1. Check that only the approximate amount of Vitamin A compound to be used per shift is in the fortification site. Open the containers only at the moment they are to be used.

2. Collect the amount of premix discharged by the feeder for one minute prior to Feeder verification. Repeat this step three times.

3. Compare the amount of premix discharged by the feeder expressed in (g/min) to the theoretical amount that should be added according to the current sugar production rate in the factory.

4. If the amount discharged does not coincide with the theoretical one, adjust the feeder and repeat steps 2 to 4 again. Record results in the prescribed form. Keep it ready to show to the Quality Control Department when required.

b. During the shift

The responsible personnel shall:

1. Check periodically that the feeder is loaded with enough Vitamin A compound, and that it is working properly.

2. Take 500 grams of sugar every hour (or every 30 minutes if production is high), mix well and detect the presence of vitamin A using a qualitative assay

3. Report any abnormality to supervisor immediately.

Commented [WU1]: CHECK BUT NOT STOP THE PROCESS

c. End of the shift

The responsible personnel shall:

1. When the shift (8-hours) ends, or more frequent if production is high, mix well eight single samples to prepare a composite sample, and label it with the date, hour and number of batch or batches. Send samples to the laboratory.

2. Record the amounts of fortified sugar produced and the quantities of Vitamin A compound used (including identification of the packaging material) during the shift.

III. Records and Reporting

Supervisor of the fortification process shall keep updated and adequately filed records of the feeder verification, amounts of fortified sugar produced and amounts of Vitamin A compound used, as well as description of actions taken during production to keep the fortification process performing as expected.

C. QUALITY CONTROL OF FORTIFIED SUGAR

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

• All sugar samples contain the minimum regulatory level of vitamin A (e.g. **>2mg/kg**4).

Commented [WU2]: See the EAC Std

• 80% of all samples to contain vitamin A levels for factory specifications (e.g. **4-12 mg/kg**) and the average concentration should be close to the target factory addition (e.g. **8 mg/kg**).

• Fortified sugar is packaged and labeled as required in the National Standards for General Labeling of Prepackaged Foods and the Sugar Fortification Regulations.

The *Quality Control Department* is responsible of this component, which should send daily reports to the *Factory Manager*.

I. Procedures

a.Supervision and sampling

The responsible personnel shall:

1. Make unannounced visits to the fortification place to check that the amount of Vitamin A compound dispatched by the feeder has been verified; the feeder contains the vitamin A compound and is working properly, and that presence of vitamin A is being checked in hourly samples using a qualitative assay. Sign to record completion of this supervision.

2. Ensure that personnel in the packaging site are taking 250 grams samples every hour (or every 30 minutes if conditions require a more frequently sampling) and mixing equal amounts of eight single samples to constitute shift composite samples which should be labeled with the day of sample preparation.

b. Vitamin A determination and Composite Sample Preparation

The responsible Laboratory personnel shall:

1.Mix well the composite samples and take 100 g sugar to determine the retinol concentration using the "Semi- quantitative method to determine retinol in fortified sugar" or the "Spectrophotometric quantitative method" if the appropriate equipment is available.

2. Plot results in the chart of **Table C-1**, expressing them in terms of vitamin A (retinol). If the semi-quantitative method is used, apply the ranges: 0-5 mg/kg, 5-10 mg/kg, 10-15 mg/kg, 15-20 mg/kg and >20 mg/kg. If the quantitative method was used write down the results in the last column intended for these results.
3. Prepare a **daily** composite sample, mixing 500 grams from each of the shift composite samples collected during the day. Mix well. Determine the content of vitamin A, and record result as *Daily comp*.

Store the remaining daily-composite sample in an air-tight and opaque container. Identify the sample with the date, and include the result of vitamin A for this sample. Keep this sample in the sample storage room for up to a month.

4. it is recommended that at least every two weeks, select randomly two daily-composite samples from the sample storage room and send them to an external reference laboratory for the quantitative determination of vitamin A.

c. Corrective actions
1. If abnormalities are found, discuss immediately with the production supervisor the measures to correct them.

III. Records and Reporting
The responsible personnel shall:

1. Complete in the appropriate form the data provided by the production supervisor.

2. Calculate the ratio sugar produced/premix. For example, if the target vitamin content is 7.5-8.0 mg/kg, the ratio should be close to 2.0 in weight (MT sugar/kg premix) or 1000 if it is expressed in 50-kg sacks sugar over 25-kg bags premix5.

3. Record all the needed information in the prscribed form and send daily a copy to the production manager for attention.

4. Once results *Results* from external laboratory are received, record those in the appropriate form intended for quantitative results; specify which samples were analyzed and that results come from an external laboratory. Compare the results with your own data, and if incompatibility is found look for the reason, and apply corrective measures as needed.

5. Send reports to the production manager about corrective actions or confirmation of the prior conclusions and deductions from the work of the Quality Control Department.

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CHAPTER 5. REGISTRATION OF FORTIFIED SUGAR

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

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
3.School Outreach