RWANDA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR FORTIFICATION OF WHEAT FLOUR

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ABBREVIATIONS

1. **ECSA-HC: East, Central and Southern Health Community**
2. FAO - Food and Agriculture Organization
3. GMP - Good ManufActuring PrActices
4. HACCP - Hazard Analysis Critical Control Points
5. Rwanda FDA - Rwanda Food and Drugs Authority
6. 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 in Rwanda.

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

CHAPTER I

INTRODUCTION

Rwanda FDA has made food fortification mandatory for wheat flour. 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 wheat flour for sale in Rwanda. These products shall be fortified using **premix of Iron and Vitamin A**.

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 N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and Law N° 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 N° 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 gazetted

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 fortified wheat flour 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 wheat flour factory shall have an automated line. In addition, there shall be an additional line for fortification including batch/ continuous mixer and the packaging materials shall be opaque to prevent the loss of vitamin A due to light.

CHAPTER 2 QUALITY ASSURANCE OF PREMIX AND FLOUR PACKAGING MATERIALS RECEIPT, STORAGE AND DELIVERY

Prior to importation

Before any premix is imported in Rwanda, it shall be registered by Rwanda FDA in accordance with the guideline No….. for registration of food products.The premix shall have the shelf life of at least 75% of the total shelf life upon arrival to point of entry to Rwanda. The importer/ distributor/ agent of importers shall follow the importation procedure as detailed in the guideline No…….for import and export of food.
Before the compound is cleared in customs, inspectors shall make sure the relevant quality documents are genuine and complete .In addition, they will check if the product is still intact and safe and before being cleared for use. Check that the packages are not damaged and they are properly labeled.

Up on reception of the compound

.Sustainability of the supply chain : The factory always has enough supply of the acceptable shelf life /suitable compound in properly labeled containers for at least three (3) months of production of fortified wheat flour.
.Every time a new shipment of premix is received, check that it is in accordance with the quantity and type indicated in the purchase order. The factory shall have a system for records keeping.

• **The factory to identify the product**: the premix shall meet the specifications established for wheat flour fortification in the country such as product name, lot number, expiry date and the country of origin, address of the manufacturer /distributor/seller/agent of importer. The factory shall

test the the premix to confirm if it contains the micronutrient levels declared on the label and as presented in the Certificate of Analysis for lot.

.**Appropriate storage** : The premix shall be stored under suitable conditions and it is used on the "first-in, first-out" (FIFO) basis. Personnel directly responsible for this activity are the Warehouse manager and the Head of the Quality Control Department, who should inform the Production Manager periodically, upon receipt of Premixor whenever internal checks are done.

Procedure

a. Receipt and Storage (Warehouse**)**

1. Every time a new shipment of vitamins and mineral premix is received, the factory shall:
   -check that it is in accordance with the quantity and type indicated in the purchase order and keep the records accordingly.

   -Check that the containers are not damaged and they are properly labeled. The following information should be included: name of manufacturer and address, lot number, production and expiry dates, list of ingredients using the chemical names, micronutrient content and net weight.

-Check the results of analysis in the Certificate of Analysis correspond to the lot number of the premix delivered to the factory. The certificate should report results for every micronutrient in the premix**.** Results for moisture, granulometry and other parameters may also be included in the certificate by the manufacturer in describing the quality of the premix to the client.

4. After verification ,if the lot meets the specifications the factory shall accept it and keep records of the premix received. When a container is damaged to harm the integrity of the premix, the factory shall reject the premix and take corrective measures as per the factory GMPs.

B. Delivery (warehouse)

The responsible personnel shall :

1. When the premix is dispatched for use, 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.

Packaging materials Receipt (warehouse)

1. When the orders of new packaging materials are received from the suppliers, the responsible personnel shall check that the label is appropriate and complies with the specification, record the amount received and keep daily track of the balance.

III. Records and Reporting

The responsible personnel shall:

1.Send the Certificates of Analysis and the Specifications/Fact sheet to the Quality Control Department

2.Keep a copy of the Specifications/Fact sheet for the handling and storage instructions

3.Keep all records up to date

The records should be periodically reviewed by personnel of the Quality Control Department. Weekly reports should be sent to the Production Manager and the Quality Control department.

C. Proper use of the premix

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 premix is being used in the order of expiration date, and that records are kept up to date. Reviewer must sign on the form.

2. At least once a month, the factory shall take two 30 g samples, package them in opaque airtight container and send them to an external laboratory to confirm the vitamin A and Iron content of the premix.

3. When test results are available ,the responsible staff shall report them to the Production Manager.

4. 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.

III. Records and Reporting

Warehouse 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.

CHAPTER 3. QUALITY ASSURANCE OF THE WHEAT FLOUR FORTIFICATION PROCESS

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

- The premix is always available and properly added to the unfortified wheat flour.
- Feeder is working properly and the amount of premix discharged is in accordance with the flow of wheat flour.
- The ratio of wheat flour produced to premix used is close to the theoretical ratio calculated.

Personnel directly responsible for this component are the *production personnel* assigned to the area where fortification is taking place, with supervision by the *Quality Assurance Department*, and daily or weekly reporting to the *Production Manager.*

I. Procedures

a. Premix dilution (if applicable)

1. Depending on the type of feeder installed in the mill, it may be necessary to dilute the premix prior to its use. If this is the case, validate the mixing procedure to verify the homogeneity of the final premix. For this, take ten independent samples at random from a batch of diluted premix.

2.Send the samples to an external laboratory to determine their iron and vitamin A content quantitatively.

3.Calculate the coefficient of variation and this should be **less than 10%.**

4. The amount of premix to add to wheat flour in g/M.T. will be calculated multiplying the amount expressed in the Fact Sheet from the premix manufacturer by the dilution factor used for preparing the diluted premix in the mill.

Validation of the mixing procedure should be done before the diluted premix is used in the mill, and any time the mixing conditions are changed.
CV (%) = (Average/Standard Deviation) x 100

b. Steps to follow at the beginning of the shift

The responsible shall:

1. Check that there is enough premix in the fortification plant to use during the shift and that the premix container is properly closed.

2. When a new container is opened check that the premix is free of lumps, there is no physical contamination, and that the color is not different from previous batches. If a problem is found, contact the Production Manager.

3. If the feeder does not automatically adjust itself when the flour flow changes, prepare a reference table with the amount of premix the feeder has to discharge at different flow rates of the flour. This table should be available for the operators in charge of checking the feeder flow and preferably be displayed in the fortification section.

4. ***Feeder verification****:* To verify the performance of the feeder, collect the amount of premix the feeder discharges in one minute. Repeat this step three times.

5. Weigh the three portions collected and calculate the average, standard deviation and coefficient of variation (CV) of the collected masses. If the **CV is higher than 5%**, take another portion for one minute and calculate the average again.

6. 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 flow of the flour in the mill.

7. If the amount discharged does not coincide with the theoretical one, adjust the feeder and repeat steps 8 to 10 again to verify the adjustment. Keep the records up to date and ready to show them to the Quality Control Department when required.

c. Steps to follow during the shift

The responsible staff shall:

1. Check that the feeder is loaded with enough premix and that it is working properly.

2. Take 500 g samples of flour every hour, and check using the iron-spot test (see **Section D of the ECSA-HC manual for internal monitoring of fortified wheat flour**) that the micronutrient premix is being delivered.

3. Report any abnormality to the Production Manager.

d. End of the shift

The responsible staff shall:

1. Record the amount of fortified wheat flour produced and the quantity of premix used during the shift.

2. Calculate the ratio fortified wheat flour produced to premix used and keep record.

3. Report this information to the Production Manager and the data should always be available to show to the Quality Assurance Department when requested.

4. Prepare a composite flour sample, mixing all the hourly samples of the shift. Label it with the date, hours of shift, and batch numbers if applicable. Send the shift composite sample to the laboratory.

II. Records and Reporting

The Production Manager shall keep updated information and file records of the premix dilution done, feeder verification conducted, amounts of flour produced and amounts of premix used, as well as description of actions taken during production to keep the fortification process performing as expected.

Quality Assurance Department shall verify the amount of fortified wheat flour produced and amount of premix used from the production records and a copy of these should be kept along with the quality control records.

CHAPTER 4. QUALITY CONTROL OF FORTIFIED WHEAT FLOUR

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

• Content and spot density for iron in the wheat flour samples are comparable to those of standard wheat flour samples containing the average level of added iron expected at the factory7 (e.g. 10 mg/kg iron from added NaFeEDTA to unfortified flour).

• 80% of all samples fortified with iron and vitamin A comply with regulatory levels and the average is close to the
addition level at the factory based on quantitative methods. For example for wheat flour in the ECSA countries:

• Fortified wheat flour is packaged in new and properly labeled packaging materials as required by relevant national or international regulations for General Labeling of Prepackaged Foods and wheat flour fortification.
Quality Control Department has direct responsibility of this component, and should send daily reports to the *Production Manager.*

I.Procedures

A.Supervision and sampling

1. Personnel from Quality Control Department should make unannounced visits to the fortification place to check that the feeder has been calibrated; it contains the adequate premix and is working properly. At the the completion of the supervision exercise ,he /she shall sign in the prescribed form and keep records.

2. The responsible personnel in the packaging site shall take 500 g samples of the fortified wheat flour every hour to be used for preparing shift composite samples, and that the spot-test for iron is being used for confirming that the premix is being delivered. The composite samples must be labeled with the day and shift of the sample.

B.Using the Iron spot test

1. In the laboratory, mix well the shift composite sample and take about 250g to carry out the "*Iron Spot Test*" with semi-quantitative purposes, which are based on the density of spots in comparison with controls with known amounts of added iron.

2. Record results from the spot tests in the appropriate way to express the concentration ranges: 0-10 mg/kg, 10-15 mg/kg, 15-20 mg/kg, 20-25 mg/kg and >25 mg/kg.

3. Prepare a daily composite sample by mixing 500 grams of each of the shift samples. Mix well. Determine the content of iron in the composite of the day using the required method and keep records. Store the remnant of the daily composite sample in an air-tight and opaque container, and identify it with the brand name, date and the responsible personnel in the shift. Keep this sample in the sample-store room for up to a month.

Corrective actions

If abnormalities are found, they shall be discussed immediately with the Production Supervisor and determine effective measures to correct them.

II. Records and Reporting

The Quality Control Manager shall:

1. Collect all data provided by the production supervisor.
2. Calculate the ratio of fortified wheat flour produced/premix used.
3. Record all the required information, and send a copy of the report to the Production Manager on a daily basis.
4. Select randomly two daily-composite samples and send to an external reference laboratory for the quantitative determination of iron and vitamin A. The frequency of this analysis will depend on factory tonnage as follows:
(i) if production is less than 20 MT per day, take 2 samples every 6 months.
(ii) for production 20-50 MT, test 2 samples every 3 months and
(iii) for production above 50 MT, test 2 composite samples every month.
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 *General Manager* that include the overall performance of the fortification process, results from the external laboratory, problems found and corrective or preventive actions taken.

CHAPTER 5 REGISTRATION OF FORTIFIED WHEAT FLOUR

All fortified wheat flour 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(focus on pregnant and breast feeding mothers- prevalence of anemia)
3.School Outreach(Adolescent girls –prevalence of anemia)