RWANDA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR FORTIFICATION OF MAIZE FLOUR

OCTOBER, 2019

TABLE OF CONTENTS

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.

On the other hand, due to issues related to malnutrition, Rwanda FDA has put in place a regulation that makes mandatory the fortification of 5 food vehicles, one of them being maize flour. This has been a staple food for most of Rwandese and we believe its fortification will have a great impact on malnutrition amongst women and children as well as reduction of stunting among children.

It is our hope that users will find the document easier to follow and be encouraged to implement the fortification of their products, so as to comply with provisions of the **Law N° 003/2018 of 09/02/2018** and the fortification regulation. This will at the same time promote made in Rwanda and hence increase business for the local manufacturers by increasing access to international markets.

.....

DIRECTOR GENERAL

INTRODUCTION

Rwanda FDA has made food fortification mandatory for maize 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 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 maize flour for sale in Rwanda. These products shall be fortified using **premix of Iron, Zinc, Vitamin B complex and Vitamin A and these will be in stabilized forms**.

The guidelines comprise 6 chapters.

Chapter 1 is about the requirements for registration of processing premises. Chapter 2 shows the quality assurance of premix and flour packaging materials receipt, storage and delivery from the point of entry to the factory. Chapter 3 details quality assurance of the wheat flour fortification process including all important steps. Chapter 4 talks about the quality Control of fortified wheat flour from raw materials to finished products.

Chapter 5 details the requirements for registration of fortified maize flour products before being granted a marketing authorization in Rwanda. Finally, chapter 6 narrates the consumer awarenesss/ education needed for the guidelines to be implemented.

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.

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.

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

CHAPTER 1 PROCESSING PREMISES

GENERAL REQUIREMENTS

All fortified maize flour processing factories shall be registered and licensed by Rwanda FDA as per the provisions of the law No. 003/2018 of 9th February 2018 establishing Rwanda FDA. In general, it is the responsibility of the manufacturer of fortified maize flour to apply for licensing of premises to the Authority. 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 fortified maize flour standard- EAC standard 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 a food product.

PROCESSING EQUIPMENT

Any fortified maize flour factory shall have an automated line. In addition, there shall be an additional line for fortification including batch/ continuous mixer. All equipment shall be food grade, easy to access and clean.

CHAPTER 2 QUALITY ASSURANCE OF PREMIX AND FLOUR BAGS 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 and in accordance with the premix standards (see Felistus- EAC standard). The premix shall be manufactured from an ISO 22000 certified facility and tested from an ISO 17025 accredited lab and the test reports will be presented to the inspectors. The importer/ distributor/ agent of importers shall comply with the importation requirements 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 properly labelled, is still intact and safe before being cleared for use. The deliveries shall be accompanied by the most current material safety datasheet.

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 maize flour. Every time a new shipment of premix is received, the responsible personnel

shall 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 maize 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.
The dosage rate of the premix shall be specified on the label and the country(ies) of destination. It will also be in accordance with the EAC standard No…..

.**Appropriate storage** : The compound is stored under suitable conditions and it is used on the "first-in, first-out" (FIFO) and "first expiry, first out" (FEFO) 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 the premix or 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
- The deliveries shall be accompanied by the most current material safety datasheet.

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 of premix (warehouse)
The responsible warehouse 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.

Design a log for use.

Bag Receipt (warehouse)

1. When the orders of new bags are received from the suppliers, 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 warehouse should:

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 Head of 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. It is recommended that at least once a month, the factory should 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 should 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 MAIZE FLOUR FORTIFICATION PROCESS

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

- The premix is always available and properly added to the unfortified maize flour.
- Feeder is working properly and the amount of premix discharged is in accordance with the flow of maize flour.
- The ratio of maize 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.
NOTE: it is recommended that factories avoid the dilution of premixes as much as possible. It should only be done where/ when the doser can be highly accurate.

2.Send the samples to an external laboratory to determine their iron, zinc, vitamin B complex 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 maize 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 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 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. End of the shift

The responsible staff shall:

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

2. Calculate the ratio fortified maize 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 maize 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 MAIZE FLOUR

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

• Content and spot density for iron in the maize flour samples are comparable to those of standard maize 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). This specific form is the most ideal for maize.

• 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 maize flour in the ECSA countries:

• Fortified maize 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 maize 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 maize 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 maize 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 MAIZE FLOUR

All fortified maize flour products shall be registered by Rwanda FDA as per the provisions of the Regulation No…..for registration of pre packaged foods. During the registration exercise, the products shall be tested for micronutrients and allowed to bear the fortification logo.

CHAPTER 6 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)
Note: adolescent girls and women require higher doses of folic acid. The products here are meant for general public. NECDP to clarify their scope of awareness

RWANDA FDA
Rwanda Food and Drugs Authority