RWANDA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR FORTIFICATION OF REFINED EDIBLE VEGETABLE COOKING OILS AND FATS

OCTOBER, 2019

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ABBREVIATIONS

1.	ECSA	-	East, Central and Southern Africa 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.

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 refined edible vegetable cooking oils and fats. we believe its fortification will have a great impact on malnutrition reduction in women and children as well as 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.

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DIRECTOR GENERAL

INTRODUCTION

Rwanda FDA has made food fortification mandatory for cooking oil. 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 cooking oil for sale in Rwanda. These products shall be fortified using **Vitamin A compound and this shall be in a stabilized form (with Vitamin D3)**.

The guidelines comprise 6 chapters.

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

Chapter 5 details the requirements for registration of cooking oil 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 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 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 refined edible vegetable cooking oils and fats to apply for licensing of premises to Rwanda FDA as per the provisions of the law No. 003/2018 of 9th February 2018 establishing 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 fortified refined edible vegetable cooking oils and fats standard- EAC standard and must have been manufactured in accordance with GMP requirements prescribed under the Law.

PROCESSING EQUIPMENT

The processors of cooking oil shall have an automated system. In addition to the usual processing line, fortifying industries shall have fortifying equipment including dosimeter/ batch mixer. The dosimeter shall be calibrated every beginning of shift. Alternatively, the premix dosing can be done manually with strict observation of hygiene requirements. In this case, pre dilution in mixing tanks shall be done exponentially and shall be monitored for effective mixing.

CHAPTER 2. QUALITY ASSURANCE OF THE VITAMIN A COMPOUND PROCUREMENT, RECEIPT, STORAGE AND DELIVERY

Prior to importation

Before any Vitamin A compound is imported in Rwanda, it shall be registered by Rwanda FDA in accordance with the guideline No….. for registration of food products.The compound 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 bags for at least three (3) months of production of fortified oil.

.Every time a new shipment of Vitamin A compound 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**: Vitamin A compound meets the specifications established for cooking oil 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 Vitamin A compound to confirm its purity.

.**Appropriate storage** : The compound is 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 Vitamin A compound or whenever internal checks are done.

II. Procedures

A. Receipt and Storage (warehouse)

1. Every time a new lot of vitamin A compound is received in the factory, check that the containe are hermetically sealed and that a Certificate of Analysis (COA) has been included.

2. Records including the number of containers received, lot numbers, expiry date, country of origin , address of the manufacturer/seller/distributor/agent of importer and the name of the person who is receiving the delivery.

3. Store the containers in a clean, cool dry area and away from chemical products and direct sunlight or other potential contaminants. If possible, store the vitamin A containers in an air conditioned room.

B. Delivery (warehouse)

1. When a vitamin A container is dispatched for oil 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. Proper use of vitamin A compound

1. At least once a week, an employee of the Quality Control Department visits the warehouse and the fortification area to ensure that vitamin A 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, take two 30 g samples from the cans that will be used the day of sampling. Package them in opaque airtight container and send them to an external laboratory to confirm the vitamin A content.

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

4. Once the report from the external laboratory is received, record the results. Compare the results recorded on that day with the laboratory data, and if discrepancies exist 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.

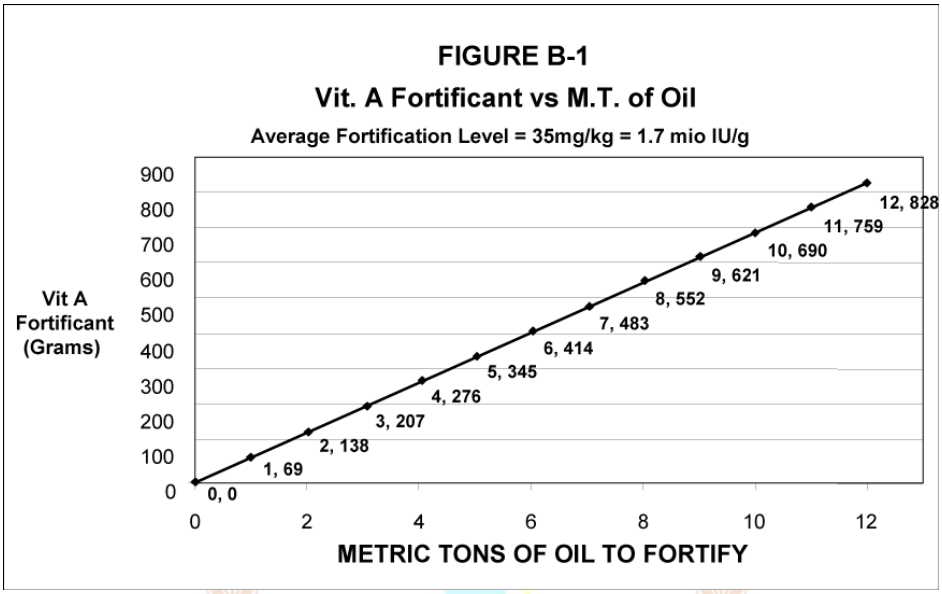
Weekly reports should be sent to the Factory Manager and the Quality Control department, where the reports will be filed.

CHAPTER 3 :QUALITY ASSURANCE OF THE OIL FORTIFICATION PROCESS

The purpose of Quality Assurance of the oil fortification process is to ensure that adequate quantities of vitamin A are added to the oil to meet the requirements of the national standard.

Fortificant (g/MT oil) = [Average Vit. content in oil (mg/kg) / Vit. A content in fortificant (g/kg)^{1}] x 1000

Fortificant (g/MT oil) = [35 (mg/kg) / 510 (g/kg)] x 1000 = 69 g/MT



Note: see the standard and align the fortification levels with the graph.

The following activities are therefore important.

1. Equipment is adequately calibrated and the pumping system delivers the vitamin A compound without leakages or delays.

2. Ratio oil produced (MT)/vitamin A compound (kg) is close to the theoretical ratio based on quantities used.

3. Vitamin A compound is adequately diluted taking into account the most recent laboratory report of the vitamin A content in the fortificant (vitamin A compound).

The responsible people for this component are the production personnel assigned to the area where fortification and packaging are taking place, lead by the Production Manager. Quality Control Department is in charge of supervising the activities and daily or weekly reporting to the Factory Manager.

I. Procedures

Typically, the vitamin A fortificant contains higher levels of vitamin A than declared in the label. This additional vitamin A is referred to as an overage and it is meant to cater for any losses than may occur during transportation and storage. The Certificate of Analysis shows the actual level of vitamin A and this should be used to calculate dilution levels. It is also necessary to confirm frequently the vitamin A content of the final product in an external laboratory (see section C).

a. Calculating the amount of vitamin A compound per batch (Production Manager) Batch System

1. Once the result of the content of vitamin A of the fortificant is received from the laboratory, estimate the amount of the fortificant that is necessary to fortify one metric ton (1,000 kg) of oil, using the equation below:

For example, if the required average content of vitamin A is 35 mg/kg (3.5 mg/100 g or 116 IU/g), and the fortificant has a vitamin A content of 1.7 million IU/g (510 g/kg), the amount of fortificant to use per metric ton of oil is:

1. Multiply the expected production in metric ton by the calculated amount of vitamin A per metric ton. A chart, such as that illustrated in Fig. B-1 will help to confirm the calculation. The chart below is based on an average vitamin A level of 35 mg/kg, while the Vitamin A fortificant has a concentration of 1.7 million IU/g (510 g retinol/kg).

Commented [WU1]: Confirm what the std says

b.Making the Vitamin A Compound (first dilution) (Production Personnel)

1. Weigh accurately the appropriate amount of the fortificant (vitamin A compound) as estimated above. Use stainless steel equipment and handle the weighing process following good manufacturing practices for food safety.

2. Add the fortificant into the blending tank, and mix for 10, 20 or 30 minutes depending on the adequate mixing time determined at the factory as described in the introduction. Record amount of fortificant that was used, as well as the time when mixing started and when mixing ended.

3. Discharge Vitamin A compound into the holding tank. Record the time accordingly. 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.

4. Weekly, check the performance of the balance, pump, and the integrity of the feeding tubes and the blending tank. Record the results of this activity carried out.

II. Records and Reporting

The Production department should keep updated and adequately filed records of the calculations done, amounts of oil 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.

Personnel directly responsible for this component are assigned to the area where fortification is taking place, with a daily supervision by the Quality Assurance Department,

and daily or weekly reporting to the Production Manager.

CHAPTER 4 : QUALITY CONTROL OF FORTIFIED OIL

•All oil samples contain the regulatory minimum level (i.e. > 10 mg/kg)1.
•80% of samples contain vitamin A within regulatory levels of 10 to 45mg/kg vitamin A and the average is close to the factory addition level of 30mg/kg.
•Fortified oil is packaged and labeled as required in the National Standards for General Labeling of Prepackaged Foods and the Oil Fortification Regulations. The responsibility for this component is the Quality Control Department, which should send daily reports to the Production Manager.

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II. Procedures

a. Collecting samples for quality control (Packaging Department)

1. Prepare a composite sample by collecting 200 mL of oil every hour, and placing in an opaque 2-L container.
2. At the end of the day label the sample with the date, hour and number of batch or batches. Include the amount of oil (in kilograms) produced during the period. Send sample to the Quality Control Department.

b. Vitamin A determination

Semi-quantitative analysis should be done hourly for each sample. In the laboratory, mix well and take 50g to use for the determination of retinol concentration using the "Semi-quantitative method for determining retinol in fortified oil", or the "Spectrophotometric quantitative method" if the necessary equipment is available (see Sections D and E for the Analytical Methods).
Based on ECSA 2007 guidelines for oil fortification.

1. Record results , expressing them in terms of vitamin A (retinol). If the semi-quantitative method is used, apply the ranges: 0-10 mg/kg, 10-20 mg/kg, 20-30 mg/kg, 30-40 mg/kg and >40 mg/kg.

2. Prepare a daily composite sample, mixing 100 mL from each of the hourly samples. Mix well. Determine the content of vitamin A for the daily composite sample and record result in Table C-1. Store the remaining daily-composite sample in an air-tight and opaque container. Identify the sample with the date, and include the amount of vitamin A from semi-quantitative testing of the Daily Comp.
sample. keep this sample in the sample-store room for up to a month.

c. Supervision (Department of Quality Control)

1. Make unannounced visits to the fortification place to check that the operators are following instructions and the records are being
filled out timely. Sign Table B-1 to confirm completion of this supervision.

2. Make unannounced visit to the packaging site to verify that the operators are taking 200-mL of oil every hour, and mixing the samples
to prepare a daily composite sample. The sample should be labeled with the date and time of preparation.

d. Corrective actions
If abnormalities are found, discuss immediately with the Production Manager the corrective actions to be taken.

I. Records and Reporting

1. Fill the appropriate forms with the data provided by the production department.

2. Calculate the ratio oil produced/vitamin A compound. The ratio should be close to 9 to 15, when expressing oil production in kilograms and amount of fortificant used in grams, depending on the type of vitamin A compound that is being used.

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3. Record all the needed information, and send a copy of the daily report to the production manager for attention and filing.

4. At least once a month, select randomly two daily-composite samples from the sample store and send to an external reference laboratory for the quantitative determination of vitamin A. Send also unfortified oil, which will be used as the blank for the laboratory.

5. Once results are received, record those in the corresponding Form. Compare the results with your own data, and if incompatibility is found look for the reason, and apply corrective measures as needed.

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.

Quality Control Department has direct responsibility of this component, and shall conduct batch testing and produce daily reports to the Production Manager.The Authority shall conduct random testing to ensure consictency as well as the protection of public health.

CHAPTER 5:REGISTRATION OF COOKING OIL

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

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
3.School Outreach
4. to preserve Vitamin A in fortified cooking oil :

- Avoiding exposure to the direct sunlight (opaque packaging materials)
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