STATUS AND COMPLIANCE OF FLOUR FORTIFICATION BY SELECTED COMMERCIAL MAIZE MILLS IN KENYA

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Status and Compliance of Flour Fortification by Selected Commercial Maize Mills in Kenya

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other university.

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DEDICATION

I dedicate this work to the Almighty God for His care and strength throughout the study period, and to my family for their unrelenting support and encouragement.

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ABBREVIATIONS

CEO: Chief Executive Officer

CMA: Cereal Mills Association

EAS: East Africa Standard

GAIN: Global Alliance for Improved Nutrition

GMP: Good Manufacturing Practices

GOK: Government of Kenya

HACCP: Hazard Analysis Critical Control Point

KDHS: Kenya Demographic Health Survey

KEBS: Kenya Bureau of Standards

Kg: Kilogram

KNMS: Kenya Nation Micronutrient survey

KS: Kenya Standard

Mg: Milligram

MOH: Ministry of Health

MT: Metric Tonne

NEMA: National Environmental Management Authority

Mg/kg: Parts per million, an equivalent of mg/kg

QA: Quality Assurance

QC: Quality Control

SPSS: Statistical Package for Social Scientists

VAD: Vitamin A Deficiency

ABSTRACT

Maize is a widely consumed staple food in Kenya. In 2012, the Government enacted mandatory legislation for maize and wheat flour fortification. This intervention was meant to reduce the prevalence of micronutrient deficiencies in the population. Despite this effort, the inclusion of fortification as part of routine milling process has remained a major challenge and most mills have no knowledge or capacity to run safe and sustainable flour fortification processes. This has been intensified by the decline in maize production and safety issues around its production, storage, processing and use. This study aimed at characterizing the commercial maize mills, determining the status and compliance of flour fortification and the retention capacity of key vitamins in fortified maize flour. Questionnaires were used as a guide for data collection on the industry characteristics while compliance and stability studies were carried out through laboratory analyses. The survey tool contained information on mill characteristics, level of training of employees, the status of implementation of flour fortification programs and food safety issues. A total of 27 brands were also procured from the market and analyzed for compliance with the national standards for vitamin A, vitamin B_2, vitamin B_3, vitamin B_9, iron and zinc. The retention capacity of micronutrients in fortified maize flour stored at 25ºC/RH 60 % and 35ºC/RH 75% for six months was also quantified. A total of 22 large, 25 medium and 31 small scale mills were surveyed. Most of the mills used roller milling technology except at small scale level where about 14% were using hammer mills. Despite the large diversity in number of employees, over 52% of the mills had less than 20% trained personnel per factory. All the large-scale mills implemented flour fortification programs, while the practice among medium and small- scale maize mills was implemented at 45.8% and 24.1% respectively. The key challenges to fortification implementation and compliance were related to low quality of dosers (69.6%) and premixes (34%), high cost of premixes (45%) and lack of skills in fortification practice and standards (55%). The level of compliance of fortified maize flour to national standards was low with only 11.1% of the samples complying in all the micronutrients analyzed (vitamin A, vitamin B_2, vitamin B_3, vitamin B_9, iron, and zinc) and Compliance status for specific micronutrients to national standards varied greatly with minerals having higher compliance levels than vitamins. About a fifth (18%) of the samples from the market did not comply with any micronutrient analyzed. The retention of the vitamins analyzed was significantly affected by storage conditions time, temperature and relative humidity ($P<0.05$). Low retention was observed for storage at 35 ºC/RH 75 % compared to 25 ºC/RH 60 %. There was evidence of low adoption of fortification programs and compliance, and safety gaps in the maize milling industry. There is, thus, need for concerted effort toward strengthening maize fortification practices among the commercial mills in the country.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Maize is one of the common staples in Kenya. It is consumed by over 85 % of the population. The per capita consumption is between 98kg to100 kg. This translates to at least 49 million metric tons per year (Ngeno. et al., 2011; Wokabi, 2013) Small-scale production accounts for about three-quarters (70 %) of the total production. The rest of the output is produced by commercial producers. Maize can be processed into a variety of products including flour, starch, corn oil, beverages, glue, industrial alcohol, and ethanol. The main forms in Kenya are maize flour and maize meal (Fiedler et al., 2014; Sürie & Wagner, 2008). Maize flour processed into thick porridge (ugali) is the most common form of maize consumed by the Kenyan population.

Prior to milling, maize is relatively high in vitamin B_1, B_6 and phosphorus. It also has fair amounts of vitamin B_2, B_3, B_7, B_9, and zinc. Most of these micronutrients, however, are lost during degerming and dehulling steps in milling (Peña-Rosas, Garcia-Casal, Pachón, Mclean, & Arabi, 2014). Over-reliance on maize and poor dietary diversity have contributed significantly to malnutrition due to micronutrient deficiencies in Kenya (Baro & Deubel, 2006; Nyariki, Wiggins, & Imungi, 2002). According to KDHS (2014) and KNBS (2011), vitamin A, iron, folate, vitamin B12, iodine, and zinc are micronutrients of public health concern in Kenya (KDHS, 2014; KNBS, 2011). The latest micronutrient survey in the country revealed that the prevalence of Vitamin A Deficiency (VAD) among pre-school children was 52.6 %; iron deficiency was at 36.1 % among pregnant women and 21.8 % among under 5 children; zinc deficiency was at 83.3 % in pregnant women and 82.3 % in non-pregnant women; and Folate deficiency was at 32.1 % in pregnant women and 30.9 % in non-pregnant women (KNBS, 2011).

Fortification of staple foods is a cost-effective approach that has been used to supply micronutrients of public health concern to the target population. Programmes like salt iodization, milk fortification with vitamin D, rice fortification with vitamin A, iron and zinc, and folic acid fortification of wheat flour and maize flour have proved to reduce the prevalence of micronutrient deficiencies in populations (Aburto, Abudou, Candeias, & Wu, 2014; Allen, Benoist, Dary, & Hurrell, 2006; Atta et al., 2016; Hamner & Tinker, 2014; Hodge & Amuna, 2014; Zimmermann & Andersson, 2012).

Following the success stories on salt iodization (Zimmermann & Andersson, 2012), the Government of Kenya (GOK) expanded the fortification programs to include other staples. The amendment of cap 264 of the Food, Drug and Substances Act and a further gazettement of the legal notice 62 on 15th June 2012 mandated fortification of maize flour, wheat flour and edible oil to set legal limits (KS 167, 168 and 170 respectively). Mandatory fortification of these staples would help achieve one of the key objectives of Vision 2030 i.e 'To improve the nutritional status and reduce micronutrient deficiencies among the vulnerable groups of the population' (Pambo, Otieno, & Okello, 2017). Cereal flours are fortified with B-group of vitamins, iron, folic acid, and zinc, while vegetable oils/fat and sugar are fortified with vitamin A (EAC, 2011; Fiedler et al., 2014; Kenya National Bureau of Statistics (KNBS); ORC Macro, 2010).

The selection of maize flour as an appropriate fortification vehicle was based on its wide consumption among all population groups regardless of the populations' wealth quintiles. Centralized large-scale processing of maize in commercial mills also allows for ease of implementation of fortification programs due to the advanced technology used in milling. Maize flour fortification practice does not affect the quality and acceptability of flour to the consumers (Wokabi, 2013; Fiedler *et al.*, 2014; Peña-Rosas et al., 2014; Enzama, 2016; KNBS, 2017).

The stability of micronutrients added to flour determines the success of a fortification program (Harika et al., 1982). Minerals are added in the most soluble forms that do not affect the flavor and odour of the fortified food while vitamins are added either as antioxidants or in encapsulated forms to improve their stability. In general, fortificants used in micronutrient premixes are selected for their stability and bioavailability (Allen et al., 2006). Antioxidants and encapsulated vitamin forms can withstand harsh environmental conditions to ensure higher retention of vitamins in fortified food (Stoltzfus et al., 2008). Retinyl palmitate, folic acid, riboflavin, and niacinamide are the most stable forms of vitamin A, Folate, vitamin B_2, and vitamin B_3 respectively while NaFeEDTA and zinc oxide are the most soluble and bioavailable forms of iron and zinc used in premixes for flour fortification (EAC, 2011; Górniaczyk, Czech-Szczapa, Sobkowski, & Chmaj-Wierzchowska, 2017).

According to Dunn (2014) and Kuong (2016), minerals are more stable than vitamins thus have a higher retention capacity. Iron and zinc have high stability during storage at high temperatures (40ºC) and high humidity (75%) for 12 months as compared to losses of up to 90 % at the highest temperature and humidity for vitamins. During food processing, distribution and storage, fortified foods are exposed to physical and chemical factors such as heat, moisture, light/air, and acid/alkaline environments. These alter the stability of vitamins leading to low retention capacity and consequent non-compliance to fortification standards (Dunn, Jain and Klein, 2014; Kuong *et al.*, 2016).

Assessing the stability of the micronutrients added to staple foods is essential in estimating the potential impact a fortification program can have. The use of premix overages to boost compliance of vitamins with standards is advised to compensate for losses during storage and cooking. However, overages have a direct impact on the sustainability of a program due to its additional cost (Dunn et al., 2014; Peña-Rosas et al., 2014).

Mandatory maize fortification aimed at providing a sustained source of micronutrients relevant to the Kenyan population in addition to replacing some essential micronutrients lost during milling (Allen et al., 2006; Peña-Rosas et al., 2014). It is assumed that all packaged flour with the Kenya fortification logo contains micronutrients within set standards, thus, consumption of such flour should confer the intended health benefits of fortification. There is, however, inadequate documented data on the maize milling practice, the extent of adoption of flour fortification programs by the commercial mills in Kenya and compliance of fortified flour to the set legal standards (Makhumula et al., 2014). Continuous surveillance and monitoring are thus necessary for effective flour fortification program implementation

This study was designed to characterize the maize milling industry, provide information on the status of flour fortification practice among commercial mills and determine the retention capacity of vitamins in fortified maize flour in the Kenyan market. This is in light of the ongoing efforts by the GOK to increase and sustain the supply of micronutrients of public health concern to the Kenyan population through fortification and improve their health status.

1.2 Statement of the Problem

In Kenya, deficiency of vitamin A, iron, folate and zinc are prevalent among the vulnerable groups of the population. As of 2011, the overall prevalence of iron deficiency among non-pregnant women is 21.9% while in rural and urban residences was 24.6% and 17.3% respectively. The prevalence of dietary iron inadequacy among women of reproductive age was 46.8%. Vitamin A deficiency was at 78% among children under 5 while zinc deficiency was 83.3%. These deficiencies have severe consequences on the population that translates to poor economic growth (KDHS, 2014; KNBS, 2011).

Folate deficiency is the leading cause of neural tube defects among children under 5 while vitamin A deficiency causes depressed immunity and xerophthalmia (Dwyer et al., 2015). Under prolonged exposure to vitamin A deficiency, night blindness then total blindness may occur (WHO, 2009). Iron deficiency causes anaemia while zinc deficiency lowers immunity (Caulfield, Richard, Rivera, Musgrove, & Black, 2006).

The Government of Kenya initiated mandatory commercial maize flour fortification so as to provide a sustained source of micronutrients of public health concern to the Kenyan population in addition to replacing some essential micronutrients lost during milling (Allen et al., 2006; Peña-Rosas et al., 2014). To date, the effectiveness of flour fortification programs is yet to be determined. There is inadequate documented data on the maize milling practice and the extent of adoption of flour fortification programs by the commercial mills and compliance of fortified flour with the EAS768 (Makhumula et al., 2014).

1.3 Justification

Food and Nutrition Security is one of the current Kenyan Government big four priority areas within the framework of vision 2030 (The African Union Commission, 2015; The Ministry of Planning and Devolution 2007). The agenda aims at increasing production of common staple foods and improving the access to nutritious food by Kenyans. Vitamin A, folate, iron and zinc are micronutrients of public health concern. Among the high impact nutrition interventions identified by the Ministry of Health Kenya to increase access to micronutrients important to health of Kenyans is fortification of staple foods (KNBS, 2011).

Fortification of staple foods is a cost-effective approach that has been used worldwide to reduce the prevalence of micronutrient deficiencies in the vulnerable groups of the population. Programs like salt iodization, milk fortification with vitamin D, rice fortification with vitamin A, iron and zinc, and folic acid fortification of wheat flour and maize flour has proved to improve the micronutrient health status in populations (Aburto et al., 2014; Allen et al., 2006; Atta et al., 2016; Hamner & Tinker, 2014; Hodge & Amuna, 2014; Zimmermann & Andersson, 2012).

In Kenya, commercial mills are mandated by law to fortify flours with B-vitamins, vitamin A, zinc, and iron. The Kenya Bureau of Standards is mandated to ensure compliance of maize flour fortification with vitamins and minerals with the fortification standard, EAS 768 (EAC, 2011; Otieno & Okello, 2011). For the effectiveness of flour fortification programs to evaluated among the population, it is important that the current practice is characterized, the status of adoption and implementation of the programs and compliance to the law evaluated. This will enable the policy makers, industry and other partners to work in collaboration towards strengthening the Kenya national food fortification programs.

Vitamins used in fortification of maize flour are prone to deterioration when exposed to the light, oxygen, high relative humidity and alkaline/acidic conditions (Dunn et al., 2014; Hemery et al., 2017; Kuong et al., 2016; Stoltzfus et al., 2008). Thus , exposure of fortified maize flour to normal storage conditions may lead to progressive deterioration of the added micronutrients and consequent non-compliance to the set legal standards (EAC, 2011). Maize flour has a shelf life of up to 6 months. However, it is uncertain that at 6 months the vitamins added during production are significantly retained. This raises concern with regard to the effectiveness of the current maize flour fortification programs in reducing the prevalence of micronutrient deficiencies in the population.

Monitoring and evaluation at output level are important in ensuring fortified flours meet desired nutrient content and safety, assessment of access by the target groups and effectively manage and sustain the fortification program to eliminate vitamin and mineral deficiencies.

1.4 Objectives

1.4.1 Main Objective

To evaluate the status and compliance of flour fortification by selected commercial maize mills in Kenya

1.4.2 Specific Objectives

1. To characterize the commercial maize milling industry and determine the status of flour fortification in Kenya.
2. To determine the key challenges for implementing and sustaining food fortification programs among commercial maize mills in Kenya.
3. To determine the level of compliance with the set legal standards for vitamin B_2 (riboflavin), vitamin B_3 (nicotinamide), vitamin B_9 (folic acid), vitamin A (retinyl palmitate), iron and zinc in fortified maize flour in the Kenyan market.
4. To determine the stability of vitamin B_2 (riboflavin), vitamin B_3 (nicotinamide), vitamin B_9 (folic acid) and vitamin A (retinyl palmitate) in fortified maize flour under storage at 25°C/RH 60% and 35°C/RH 75%

1.5 Hypothesis (Ho)

1. Commercial maize millers in Kenya have not been evaluated and characterized.
2. There are no challenges in implementing maize flour fortification by commercial millers in Kenya.
3. Commercially fortified maize flour in the Kenyan market do not conform to the set legal standards for vitamin B_2, B_3, B_9, A, iron, and zinc
4. Vitamin B_2, B_3, B_9, and A in commercially fortified maize flour is not stable under normal storage conditions.

CHAPTER TWO

LITERATURE REVIEW

2.1 Rationale for Maize Flour Fortification

2.1.1 Maize Production and Consumption in Kenya

Maize is the main staple in the diet of over 85% of the population in Kenya (Muyanga et al, 2006). The per capita consumption ranges between 98-100 kg that translates to at least 2.7M metric tons per year. Small scale production accounts for about 70% of the overall production and the rest of the output is by the commercial producers. Small scale producers mainly grow the crop for subsistence (Ngeno. et al., 2011; Wokabi, 2013).

Maize contains approximately 72% starch, 10% protein and 4% fat supplying an energy density of 365 kcal/100g. It too contains many of the B group of vitamins and essential minerals along with the fibers. However, it lacks vitamin B_{12}, vitamin C and is a poor source of calcium, folate, and iron (Gupta & Varshney, 2013; Ranum & Pe, 2014)

Outer layer- layer of the epidermis and several thin layers (bran). It is rich in fiber, minerals, oils and B-vitamins
Germ-rich in B vitamins, oils and minerals
Endosperm-high in starch and proteins

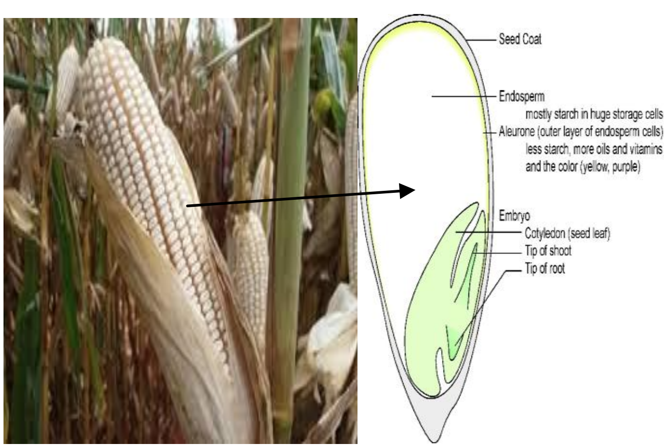


Figure 2.1: Cross-section of maize grain (Gupta & Varshney, 2013)

2.1.2 Maize Milling

Maize is processed into different food and industrial products. Such products include flour, maize meal, beverages, corn starch, sweeteners, corn oil, glue, industrial alcohol, and ethanol. The main forms in Kenya, however, are maize flour and maize meal. Milling of maize into flour involves cleaning and conditioning of the grains before wet or dry milling (Gwirtz & Garcia-Casal, 2014). The process involves degerming and dehulling that leads to loss of most vitamins and minerals (**Table 2.1)**. Such micronutrients can be replaced through fortification (Fiedler et al., 2014).

Table 2.1: Micronutrient losses during maize milling

Type of Micronutrient	Whole Maize	Dehulled Flour	Degermed Flour
Vitamin A	0	-	-
Thiamin, B1	4.7	4.4	1.3
Riboflavin, B2	0.9	0.7	0.4
Niacin, B3	16.2	13.9	9.8
Pyridoxine, B6	5.4	5.4	1.9
Vitamin E	0	-	-
Folate	0.3	0.2	0.1
Biotin	0.073	0.055	0.014
Calcium	30.8	26.7	14.5
Phosphorus	3100	2500	800
Zinc	21.0	17.1	4.4
Iron	23.3	19.7	10.8

Source: Gwirtz & Garcia-Casal, 2014

2.1.3 Maize Flour Fortification

Maize flour is an appropriate fortification vehicle as it is industrially produced and consumed by 40% of Kenyans (commercially milled maize flour) (Fiedler et al., 2014; Wokabi, 2013). Some of the considerations for maize flour fortification include the nutritional needs and deficiencies of the people, the consumption profile of maize flour, the sensory and physical effects of fortificant on the flour and the costs. Fortification does not affect the quality or acceptability of the flour (Peña-Rosas et al., 2014). Fortification can also be used to supply micronutrients of public health concern to the population. This is the case of fortification of maize flour by vitamin A, folate, iron and zinc to specific set standards.

Flour fortification programs include quality control by the mills and the regulatory, and public health monitoring of the nutrients content of fortified flour and assessment of the nutritional impact in the target population upon consumption. Fortification is carried out mostly by the large scale mills, a few medium-scale mills and rarely by the small scale mills.

Some of the micronutrients added to maize flour include B-group of vitamins, folate, vitamin A, zinc and iron in different premix forms (**Table 2.2**). Some of the considerations during fortification are the process of adding micronutrients to the flour and the selection of the dossiers or feeders. Dosing should ensure uniform distribution of the nutrients in the flour at the mill, during storage and in the flour on preparation. These micronutrient premixes are added commonly on the screw-type conveyor before packaging or when flours from different batches converge.

The stability of the nutrients, especially vitamins in the case of maize flour, is affected by such storage factors as temperature, moisture content, light, pH, Oxygen, length of storage and packaging among others (Dunn et al., 2014; Hemery et al., 2017).

Table 2.2: Maize Flour Fortificants

Micronutrient Type		Premix
Vitamin A		Retinyl Palmitate
B complex	B_1	Thiamine mononitrate
	B_2	Riboflavin
	B_3	Niacinamide
	B_6	Pyridoxine
	B_9	Folic acid
	B_{12}	Vitamin B_{12} 0.1% wt.
Iron		NaFe EDTA
Zinc		Zinc oxide

2.4.3.1 Maize flour fortificants

Vitamin A

Vitamin A belongs to the retinoid group of compounds (retinal, retinol and retinoic acid) and provitamin A carotenoid (natural plant pigments). While approximately 90 % of retinoid is absorbed in the body, less than 5% of provitamin A carotenoids are absorbed. The dietary sources of provitamin A include vegetables such as carrots, pumpkin, papaya, and red palm oil. Human milk and animal sources are rich in preformed Vitamin A (Beltrán-de-Miguel, Estévez-Santiago, & Olmedilla-Alonso, 2015).

Maize and its products do not contain vitamin A with the exception of yellow maize that contains provitamin A carotenoid (Mwaniki, 2007). Vitamin A is unstable under normal environmental conditions thus commercial retinol preparations for fortification are esterified with palmitic or acetic acid to improve their stability (Saeterdal, Mora, & De-Regil, 2012). Vitamin A is fat-soluble thus is easily added to fat-based or oily foods. If the food vehicle is dry, in this case, maize flour, an encapsulated form of the vitamin is used. Encapsulated retinyl acetate and retinyl palmitate are the main forms used in maize flour fortification. Retinyl palmitate is provided in dry powder form that protects against light and humidity (Johnson, Mannar, & Ranum, 2004)

Vitamin B_2 (Riboflavin)

Vitamin B_2 is a compound of two coenzymes that help in energy metabolism of food. The recommended compound for flour fortification is Riboflavin (Johnson et al., 2004)

Vitamin B_3 (Niacin)

Niacin is important in energy, fats and protein metabolism of food (Meng et al., 2018). Pellagra, a clinical manifestation of niacin deficiency, is associated with diets that heavily rely on maize as a staple food (Hannon, Kiely, & Flynn, 2007). The common form of niacin used in fortification is nicotinic acid and nicotinamide (Allen et al., 2006).

Vitamin B_9 (Folate)

Folate encompasses folic acid and folate monoglutamate (Dwyer et al., 2015). These two forms are water-soluble. Folic acid is the synthetic and most stable form of folate that's often used in supplements and fortified foods (Hamner & Tinker, 2014). Folates are known to be sensitive to heat, oxygen, light and acidic environments (Surma, 2010) . In normal storage of maize flour, such conditions are exhibited thus the possibility of low retention of the vitamin. Losses could be up to 50-90% in storage (Food Standards Australia New Zealand, 2006).

Iron

Selection of iron fortificant to use in fortification depends on bioavailability, maximum concentration that can be added without impacting sensory quality, cost, and availability. However, bioavailability, stability and sensory effects of iron premixes are the most important (Dary, Freire, & Kim, 2003; Moretti, Biebinger, Bruins, Hoeft, & Kraemer, 2014; Oikeh, Menkir, Maziya-Dixon, Welch, & Glahn, 2003; Uauy, Hertrampf, & Reddy, 2002). The recommended iron compounds for maize flour fortification include ferrous sulfate, elemental iron powders, ferrous fumarate and NaFeEDTA (Dary et al., 2003).

Ferrous sulfate has high bioavailability and has been used in bread, pasta, and infant formula. However, it is not acceptable in flour as it impacts objectionable flavors, especially during storage (Peña-Rosas et al., 2014). Ferrous fumarate has bioavailable iron and overcomes the effects of taste. Electrolytic iron compounds added to cereals have poor bioavailability and affect the taste of flour at concentrations that would produce the required dietary intake. EDTA is the most preferred premix and is thus mostly used in maize flour fortification (Johnson et al., 2004). It protects iron against dietary inhibitors, has superior bioavailability and do not impart flavor to flour (Uauy et al., 2002)

Zinc

The choice of zinc compounds in premix used in fortification is based on solubility, taste, cost, side effects and safety (Johnson et al., 2004). Water-soluble compounds (zinc EDTA, zinc acetate, zinc gluconate, and zinc sulfate) are more readily absorbed than compounds of limited solubility at neutral pH. Zinc oxide and zinc sulfate are considered cheap thus most commonly used (Moretti et al., 2014). In Kenya, zinc oxide is the main fortificant used in maize flour.

2.4.4.2 Stability of key micronutrients used in fortification

The success of a food fortification program depends on the stability and bioavailability of the micronutrients used. Physical and chemical factors that affect Micronutrient stability include heat, moisture, exposure to light/air, and acid/alkaline environments. During food processing, distribution and storage, the stability of vitamins is altered thus the need to use stabilized encapsulated forms of vitamins to improve their resistance to these conditions (Dunn et al., 2014; Stoltzfus et al., 2008).

In general, fortificants used in micronutrient premixes are selected for their stability and bioavailability. Antioxidants and encapsulated forms withstand the harsh environmental conditions during storage and cooking to ensure consumers get the required amounts of vitamins from the diets for maximum health benefits.

According to Dunn, 2014 and, Kuong, 2016, minerals are more stable than vitamins thus have a higher retention capacity. Iron and zinc have high stability of during storage at high temperatures (40ºC) and high humidity (75%) for 12 months as compared to losses of up to 90% at the highest temperature and humidity for vitamin A (Dunn et al., 2014; Kuong et al., 2016).

Assessing the stability of the micronutrients added to staple foods is essential in estimating the potential impact of a fortification program. Any overages to be added to compensate losses during storage and cooking have a direct impact on the sustainability of a program due to the additional cost.

2.2 Micronutrient Malnutrition

Micronutrients are important in sustaining life and optimal physiological functioning of the body. Micronutrient malnutrition, however, is a major problem in the world. It is the lack of essential micronutrients to the body that makes one susceptible to infections (Hodge & Amuna, 2014). Iodine, iron, vitamin A and zinc deficiencies are the most common micronutrients of public health concern worldwide as they contribute to poor growth, intellectual impairments, perinatal complications and increased risk of morbidity and mortality (Bailey, 2015; Bhutta et al., 2008; WHO, 2014).

Over 2 billion people are micronutrient deficient in the world (Challenges, 2007). The prevalence, however, is high in developing countries where infants, young children, and women of reproductive age are the most vulnerable. Micronutrient deficiencies account for an estimated 7.3 % of the global burden of disease, with iron and vitamin A deficiencies being among the leading causes (Allen et al., 2006; WHO, 2014).

Micronutrient deficiency has negative effects on human health and cognitive functions (Delgado, 2003; Food, Policy, Survey, & Standards, 2011). Besides the direct health effects, the existence of 'hidden hunger' affect the economic development and productivity of a country in terms of public health costs and loss of human capital (Challenges, 2007). According to the Kenya National Micronutrient survey, 2011, the micronutrients of public health concern in Kenya are iron, vitamin A, iodine, folate, B12, and zinc (KNBS, 2011).

2.2.1 Iodine Deficiency

Iodine Deficiency Disorders are of public health concern worldwide affecting all groups of people. However, children and lactating women are the most vulnerable. At a global scale, approximately 2 billion people suffer of iodine deficiency (ID) with approximately 50 million presenting clinical manifestations (Biban & Lichiardopol, 2017). Iodine deficiency is an important preventable cause of brain damage. Severe iodine deficiency causes goitre and hypothyroidism because it impairs thyroid hormone production (Keith P. West, Jr., 2006). Iodine is required to produce thyroid hormones that control cell metabolism, neuromuscular tissue growth and development, especially the fetal perinatal brain (WHO, 2007). In Kenya, despite the adoption of universal salt iodization, the prevalence of iodine deficiency was 22.1% among school age children and 25.6% among non-pregnant women (KNBS, 2011).

2.2.2 Iron Deficiency, Iron Deficiency Anaemia, and Anaemia,

Over 1.6 billion people in the world are anaemic with the highest prevalence among preschool children, school children, and women. This condition is associated with impaired cognitive and motor development in children and an increased risk of maternal and neonatal mortality (Sullivan et al., 2012).

Anaemia occurs both in industrialized and developing countries with a prevalence of over 90 % in low-income countries. The primary cause of anaemia is iron deficiency accounting for an estimated 50 % of anaemic cases (Bratter & Bratter, 2000). Iron deficiency anaemia is a severe stage of iron deficiency in which hemoglobin (hematocrit) falls below the standard cut-offs (Stoltzfus& Dreyfuss, 2000). Iron deficiency anaemia may coexist with malaria, parasitic infection and nutritional deficiencies of vitamin B_9 (folate), vitamin B_{12} and vitamin A (Butler et al., 2012; Kai & Roberts, 2008; Smith & Brooker, 2010; World Health Organization, 2011).

Iron deficiency occurs mostly during times of increased need. This is common in children when rapid growth is desirable resulting in expansion of red blood cells, in adolescents when growth and red blood cell production increases and in women on the onset of menstruation that's associated with blood loss and during pregnancy when blood volume expands (Garcia-Casal, Peña-Rosas, De-Regil, Gwirtz, & Pasricha, 2018). Iron deficiency affects the social and economic development of the country (Seshadri, 2001).

In Kenya, the prevalence of iron deficiency anaemia is at 26% in pregnant women, 12.5% in preschool children, 14% in school-aged children and 21.8% in non-pregnant women. The overall prevalence of anaemia in Kenya was at 23.1 % compared to 24.8% globally and 40.7% in Africa (KDHS, 2014; KNBS, 2011).

2.2.3 Zinc Deficiency

Zinc deficiency is widespread globally particularly in children and women residing in low and middle-income countries thus require public health intervention (Shah, Sachdev, Gera, De-Regil, & Peña-Rosas, 2016). The prevalence has been noted to be high in South-East Asia and Africa (Allen et al., 2006).

Zinc deficiency is responsible for approximately 4% of deaths and 16 million disability-adjusted life years (DALYs) among children under age 5 in lower-income countries and is usually associated with the iron-deficient population (Schofield et al., 2008). Deficiency of zinc in children leads to diarrhea, impairment of cognitive function and behavioral problems, hair loss, inflammation of the eyelids and conjunctiva, growth retardation and recurrent infections in the elderly.

The prevalence of zinc deficiency in Kenya is 83.3 % among all population groups, 82.3 % for non-pregnant women, 80.2 % among school-aged children, 74.8 % in men and 68.3 % in pregnant women (KNBS, 2011).

2.2.4 Folate Deficiency

Folate is a major coenzyme in one-carbon metabolism including DNA synthesis and methylation. These important roles in cellular homeostasis are associated with increased risk for several diseases including cancer, Alzheimer's disease, thrombogenetic and atherogenesis vascular disease including hypertension (Dwyer et al., 2015). They also influence the underlying mechanism that explains the deficiency disease of folic acid megaloblastic anaemia (Das, Salam, Kumar, & Bhutta, 2013; De-Regil, Finkelstein, Sæterdal, Gaitán, & Peña-Rosas, 2016; Flour Fortification Initiative (FFI), 2008).

Adequate folate consumption is necessary for women of childbearing age. This is because neural tube development occurs during the first trimester before most women realize they are pregnant (Hamner & Tinker, 2014). This is more relevant as over half of all the pregnancies are unplanned thus insufficient maternal folate status is the major risk for neural tube defects along with other genetic, geographic or socioeconomic causes

(Das et al., 2013). In Kenya, the prevalence of folate deficiency is at 32.1% among pregnant women and 30.9% among non-pregnant women (KNBS, 2011).

2.2.5 Vitamin A Deficiency

Vitamin A deficiency (VAD) is an important cause of preventable childhood blindness. It is a significant public health problem in low and middle-income countries among young children, women of reproductive age and pregnant women. VAD contributes to approximately 6% of child deaths under 5 in Africa and 8% in South-East Asia (Bryce, Coitinho, Darnton-Hill, Pelletier, & Pinstrup-Andersen, 2008; WHO, 2009).

Deficiency occurs on a prolonged lack of an adequate intake of vitamin A. Infections such as diarrhea, measles, and malaria may also make one susceptible to VAD (Bratter & Bratter, 2000). VAD has consequences throughout life and affects health and physical performance of the population. Infants and young children have increased vitamin A requirement to support rapid growth and help prevent the risk of infections. In pregnancy, vitamin A is essential for fetal growth and maturation, maintenance of maternal immunity, eye health and night vision (WHO, 2009).

The prevalence of Vitamin A deficiency in Kenya, based on the retinol-binding protein values was at 24.2%. Preschool children have a marginal VAD prevalence of 52.6%, while in pregnant women the prevalence is at 21.6% (KNBS, 2011).

Multiple micronutrient deficiencies may co-exist in a population. Their long term impact is deleterious on economic development and human capital at the country level. There is thus an actual need to increase the intake of these essential nutrients among the vulnerable groups.

2.3 Interventions to Reduce Micronutrient Malnutrition in Kenya

In Kenya, despite the significant progress in increasing food production and reducing food insecurity, achieving sustainable food security is still a challenge. The prevalence of micronutrient deficiencies is still high (KNBS, 2011). The government developed a National Food Security and Nutrition Policy and Strategy with the objective of 'ensuring that all Kenyans throughout their life cycle enjoy, at all times, safe food in sufficient quantity and quality to satisfy their nutritional needs for optimal health' (Mburu, Thurnham, Mwaniki, Muniu, & Alumasa, 2010).

Prevention of micronutrient deficiencies has been addressed through the following interventions including micronutrient supplementation for specific population groups, fortification of specific staple foods, dietary modifications and diversity and bio-fortification (KNBS, 2011)

2.3.1 Micronutrient Supplementation

The World Health Organization (WHO) recommends vitamin A supplementation to infants and children between 6-59 months of age as a public health intervention in cases where VAD is a problem to reduce child morbidity and mortality. Where a population is at risk of VAD, supplementation reduces mortality in children between 6 months to 5 years by 23% (WHO, 2009). In supplementation efforts in Kenya, there has been routine and accelerated vitamin A supplements for children 6-59 months and postpartum women within 4 weeks after delivery. According to the Ministry of Health-Kenya, 84.3% of children under 5 received vitamin A supplementation in 2011 (KNBS, 2011).

Iron and folate supplementation has been implemented in the maternal and child health (MCH) clinics and other health service delivery outlets for pregnant women. Daily supplementation with iron and folic acid for a period of 3 months has been the standard approach of preventing and treating fetal NTD. During pregnancy, 49.7% of women received iron supplements and 31.6% received folate supplements. Intermittent use of oral iron supplements is an effective alternative to daily iron supplementation to prevent anaemia among menstruating women (KNBS, 2011). Iron supplementation during pregnancy lowers the risk of maternal mortality, premature births, and low birth weight while sufficient folate levels in women prior to conception has been shown to reduce the cases of NTD by half (Christianson, Howson, & Modell, 2006; Grant, 2016).

Zinc supplementation has also been implemented among children with diarrhoea (KNBS, 2011). Zinc supplementation given with oral rehydration therapy has proved to reduce the incidences of diarrhea in children by 27% and acute lower respiratory tract infection by 15% (Bown, Hess, & Ave, 2010).

2.3.2 Dietary Diversity

Dietary diversity is important in improving the nutrition status of the population as it ensures adequate nutrient intake (Hoddinott & Yohannes, 2002). Dietary problems are common in underprivileged areas such as rural areas during seasonal food shortages or urban areas under acute poverty. Since no single food contains all the necessary nutrients, diversifying dietary sources ensures a balanced and healthy diet (KNBS, 2011).

Dietary diversity is determined by counting the number and selection of food groups based on their unique contribution to the nutrient adequacy (Hoddinott & Yohannes, 2002; Wagah, Bader, Deligia, & Dop, 2005). The food group indicator is based on the following food groups; grains, roots, and tubers, legumes and nuts, dairy products, flesh foods- meats, fish, poultry, liver and organ meats, eggs, vitamin A-rich fruits and vegetables and other fruits and vegetables

The dietary diversity score is a useful and simple indicator for assessing diet quality (Ruel, 2003). Children with a score of less than 4 are considered to have inadequate dietary diversity (Meng et al., 2018; Steyn, Nel, Nantel, Kennedy, & Labadarios, 2006).

2.3.3 Biofortification

Bio-fortification involves the use of agronomic practices, conventional plant breeding, and modern biotechnology to improve the nutritional quality of food crops (Mwaniki, 2007; WHO and FAO, 2007). It is aimed at increasing the nutrient levels in crops during plant growth. It is effective in reaching populations where supplementation and conventional fortification is not feasible. Rural populations that rely on small scale maize farming and prefer to mill their own maize could benefit from Bio-fortification to address their micronutrient needs.

The effectiveness of bio-fortification to improve micronutrient intake in populations depends on such factors as a supportive legal framework, adequate breeding, production and supply of fertilizer and bio-fortified seeds and crops, and the integration of bio-fortified crops into food systems (Bouis, Low, McEwan, & Tanumihardjo, 2013).

2.3.4 Fortification of Staple Foods

Fortification is a cost-effective intervention used to control micronutrient deficiencies in the population (Darnton-Hill & Nalubola, 2002; Zamora & De-Regil, 2014). It is most feasible for the population that consumes centrally processed foods. Fortification uses existing technology and local distribution networks (Allen et al., 2006). Fortification could be voluntary or mandatory. In mandatory fortification, the food manufacturers have to fortify to specific legal standards with a bioavailable fortificant that can be accessed by the consumers. This fortificant should not alter the sensory characteristics of the food. For the desired health impact, however, adequately fortified foods have to be consumed in adequate amounts by the target population (Allen et al., 2006).

With respect to the fortification of staple foods, Kenya has made concrete steps to expand the number of fortification vehicles and increase the production of fortified foods. It has also mandated certain staple food manufacturers to fortify their products to specific set standards. All commercial mills are mandated to fortify their flours (wheat and maize flour) with specific micronutrients of public health concern to Kenyans. Sugar and vegetable oil producers are also required to fortify with vitamin A. These products are regularly monitored by the Kenya Bureau of Standards, KEBs to ensure compliance. Nutrition surveillance systems are in place to assess the impact of this intervention in improving the health of the population.

2.3.4.1 History Food Fortification in Kenya

More than 2 billion people worldwide suffer from micronutrient deficiencies as they are unable to meet their daily requirements of essential minerals and vitamins (Global Report, 2009). Some programs implemented to reduce the prevalence of micronutrient deficiencies include: salt iodization, milk fortification with vitamin D, calcium and vitamin D fortification of juices, fortification of bread with omega-3 fatty acids and vegetable oil spreads with plant sterol among others. Diseases that were a worldwide problem in the early 20th century such as goiter, rickets, beriberi, and pellagra have been reduced following food fortification (Allen et al., 2006; Hodge & Amuna, 2014).

According to Future and Relations (2014), food fortification can take several forms. These include mass fortification; targeted fortification; or household fortification. Globally, the decision to fortify food products is left up to the manufacturers. Voluntary fortification thus is a common practice in most countries. Some countries, however, require mandatory fortification of certain staple foods with specific micronutrients to specified standards to improve public health. This is common in countries where there is a demonstrated need to improve the micronutrient health of the population (Allen et al., 2006; Hodge & Amuna, 2014).

Food fortification in Kenya dates back to 1978 when the government of Kenya made iodization of salt mandatory. This led to a reduction in the total goiter rate to below 7 % (Darnton-Hill & Nalubola, 2002). Following universal salt iodization, more efforts were put in place voluntarily by different actors to fortify other foods e.g. cereal flours with B-group of vitamins, iron, folic acid and zinc, and oils, fats, and sugar with vitamin A.

In 2001, Capwell mills started fortification of 'Pendana' maize flour while Unga Limited fortified 'Jogoo Extra' and 'Hostess' maize meal. In 2006, The Kenya national food fortification alliance was formed to spearhead the food fortification programs. A fortification logo was developed and adopted. Fortification guidelines and standards for maize and wheat flour were also developed and adopted and the certification process for fortified flour and oil developed. In 2011, the government of Kenya with support from the Global Alliance in Nutrition (GAIN) initiated a project to accelerate food fortification in the country. The project was implemented from 2011-2015.

In May 2012, the National Quality and Inspection guidelines were developed. In June 2012, Kenya Foods, Drugs, and Chemical Substance Act was amended to include the mandatory fortification of fats/oils, maize and wheat flours with specific vitamins and minerals. In addition, a gazette notice was issued (Kenya Gazette supplement no. 62 cap 254) which made fortification of fats/oils, maize, and wheat flours mandatory. Kenya's commitment to improving nutrition is established in vision 2030, the country's development blueprint and is also aligned with the government's broader Medium-term Development plan (MDGs).

2.3.4.2 Food fortification Legislation and Standards

It is the role of the government to protect public health; it is recommended that all forms of food fortification be appropriately regulated to ensure the safety of the consumers and maximum benefit to the target groups. Fortification can be categorized as mandatory or voluntary in the legal context. This is based on the level of obligation required for food producers to comply with the government intentions expressed in the law. Food fortification is currently coordinated by the Ministry of Health under the Nutrition and Dietetics Unit (NDU). It is implemented through a multi-sector approach with the public-private sector partnership that brings together stakeholders from the Kenya National Food Fortification Alliance, KNFFA (**Figure 2.2**).

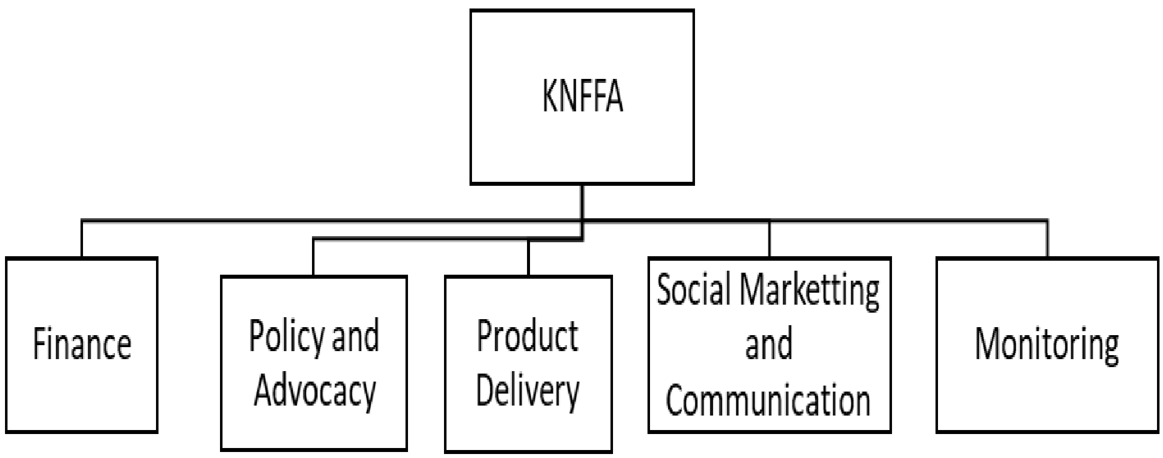


Figure 2.2: Structure of KNFFA functions (Otieno & Okello, 2011)

The regulation on mandatory fortification was then revised through legal notice 157 of 24th July 2015 which states in part that: Packaged wheat flour shall be fortified and conform to the food requirements specified, packaged dry milled maize products shall be fortified and conform to the requirements specified, vegetable fats and oils shall be fortified with vitamin A in accordance with the Kenya Standard for edible fats and oil and labeling of fortified products shall be done in accordance with the relevant East Africa standards relating to nutrition.

Mandatory fortification provides a higher level of certainty that the food will deliver a sustained source of micronutrients relevant to public health benefits (Allen et al., 2006). It occurs when the government legally obliges food manufacturers to fortify particular food with specific micronutrients to specified standards. In this regard, the government ensures that the food vehicle and the fortificants are safe, efficient, and effective for the target population group

Mandatory fortification in Kenya include commercial flours, with B-group of vitamins, vitamin A, folate, zinc and iron, sugar with vitamin A and vegetable oil with vitamin A. This was based on the high proportion of the general population having a significant public health need, or at risk of being or becoming deficient in the specific micronutrients (KDHS 2008).

Applicable National Standards

There are two categories of standards that food processors need to comply with in regard to fortification. They include product standards and labeling standards.

Product standards

These provide minimum requirements for the respective products. Following mandatory fortification in Kenya, the following product standards are applicable:

Wheat Flour

Table 2.3: Wheat flour fortification standards- KS 169/KS EAS 767 (EAC, 2011)

Nutrient And Form	Requirements (Mg/Kg)
Vitamin A: vitamin A palm.SD	0.5-1.4
BI: Thiamine mononitrate	4.6
B2: Riboflavin	3.3 min
B3: Niacinamide	30 min
Folates: Folic acid	1.1-3.2
B6: Pyridoxine	3min
B12: vit.B12 0.1% WS	0.01min
Iron: ferrous fumarate	30-50
Zinc: zinc oxide	40-80

a) Maize flour

Table 2.4: Maize meal fortification- KS 168/ KS EAS 768 (EAC, 2011)

Nutrient and Form	Requirements (Mg/Kg)
Vitamin A: vitamin A palm.SD	0.5-1.4
BI: Thiamine mononitrate	3.0 min
B2: Riboflavin	2.0 min
B3: Niacinamide	14.9 min
Folates: Folic acid	0.6-1.7
B6: Pyridoxine	2.0 min
B12: vit.B12 0.1% WS	0.007 min
Iron: ferrous fumarate	21-41
Zinc: zinc oxide	33-65

b) Edible Oils-KS EAS 769

20 – 40 mg/kg of vitamin A expressed as Retinol. The compound should be Retinyl Palmitate

c) Edible Salt-KS EAS 35

30 – 60 mg/kg of Iodine, using potassium iodate

d) Sugar-KS EAS 770

2 – 15 mg/kg of vitamin A, using retinyl palmitate

e) KS 2571, Requirements for the supply of premix in Kenya
f) KNWA 2393, Guidelines for monitoring of fortified products

Labeling standards

They provide the minimum requirement that each of the packaged foods must have. Two primary standards applicable to prepackaged foods are labeling of prepackaged foods, KS EAS 38 and guidelines for health and nutrition claim, KS CAC/GC23. It is assumed that all packaged flour with the fortification logo (**Appendix I**) contains micronutrients within set standards thus consumption of such flour should confer the intended health benefits of fortification.

2.3.4.3 Appropriate Food Fortification vehicles

Food fortification vehicles generally range from basic commodities that are available on the retail market for use by the consumers as well as ingredients of processed foods, to processed foods that are fortified at the point of production. Processed formulated foods are a better vehicle for targeted fortification initiatives while basic commodities are suited for mass fortification (Allen et al., 2006; GAIN, 2012). In Kenya the staples that have been selected for mandatory fortification are salt, wheat flour, maize flour and vegetable oil while sugar is voluntarily fortified by the producers (KNBS, 2011).

2.4 Monitoring and Evaluation

Food fortification is a cost-effective food-based approach that has been used to control micronutrient deficiencies among the population. A critical component of these programs is to provide ongoing information on the progress of implementation and to ensure the intended health impact among the target population (Luthringer, Rowe, Vossenaar, & Garrett, 2015; van den Wijngaart, Bégin, Codling, Randall, & Johnson, 2013).

All monitoring and evaluation activities outlined in **Figure 2.3** are integral to effective fortification program. Regulatory monitoring, however, is the work of food technologists and food control units

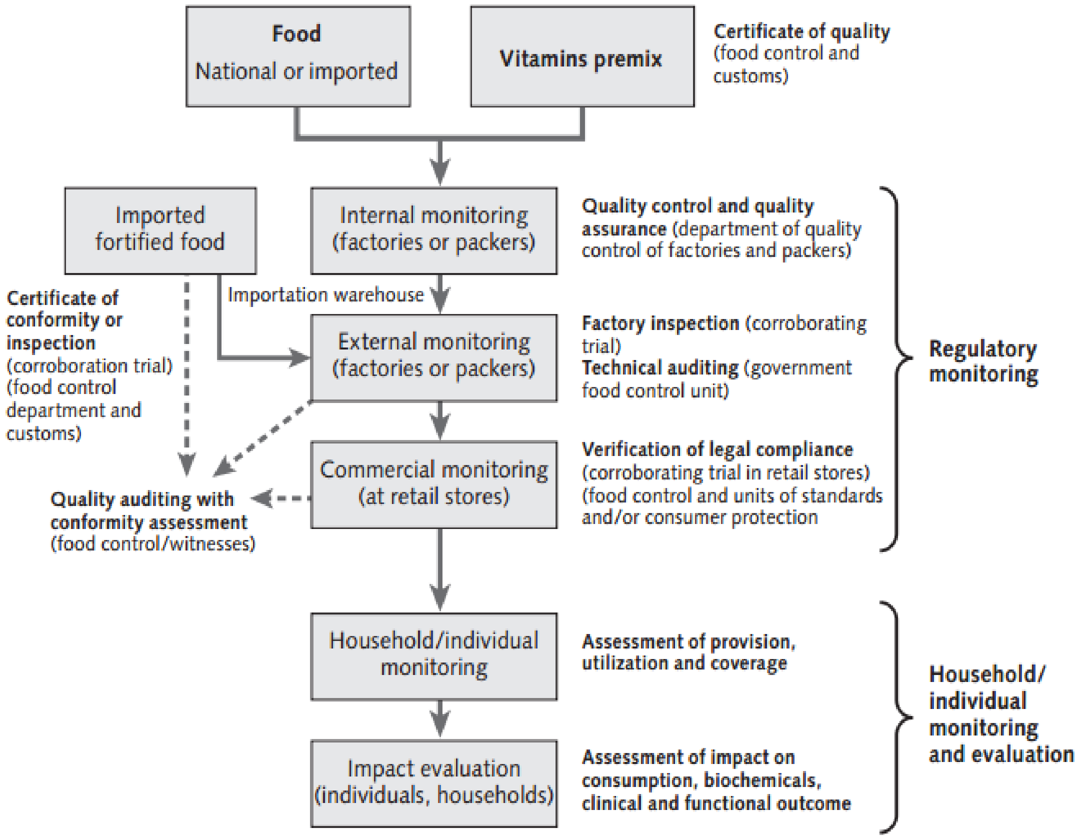


Figure 2.3: The framework for monitoring and evaluation of the fortification program (Allen et al., 2006)

The main components of food fortification programs are supply and control of adequately fortified foods both nationally produced and imported and population access and utilization of fortified foods (dissemination, acceptance, consumption, and impact) (Pena-Rosas, Parvanta, Van Der Haar, & Chapel, 2008). Regulatory monitoring has legal implications and typically involves certification of the micronutrient premix, internal monitoring in the factories (quality control and quality assurance), external monitoring (inspection and auditing) and commercial monitoring (verification of compliance at distribution centers and retail stores) (Allen et al., 2006; Luthringer et al., 2015).

Premix monitoring in Kenya is done by the Kenya Bureau of Standards. National regulations specify a required formulation for the fortification premix and prescribe that mills purchase premix from specified suppliers. Such suppliers have to be licensed by the government (KEBS, 2012).

Internal monitoring at the production level involves different quality control and quality assurance activities by the mills to ensure compliance. Daily physical checks of the quantity of premix delivered, check on premix usage, a visual check that the micro-feeder is working properly and rapid chemical tests are important (Johnson et al., 2004). Iron spot test has been commonly used in quality control of iron fortification.

External monitoring at production and retail level is a powerful tool in the evaluation of the projected impact of the micronutrient intervention. Compliance with standards set by the national government indicates that the desired nutrients in projected amounts are consumed by the target population. The Kenyan fortification legislation mandates all commercial maize mills to fortify their flour to the set legal standards (KS 168/EAS 768). This does not, however, guarantee quality fortified maize flour. Continuous surveillance and monitoring, both internal and by regulatory bodies is necessary for effective flour fortification program implementation (Enzama, Afidra, Johnson, & Verster, 2017; Makhumula et al., 2014). External monitoring at production and retail level is a powerful tool in the evaluation of the projected impact of the micronutrient intervention. Compliance with standards set by the national government indicates that the desired nutrients in projected amounts are consumed by the target population. This is mandated to KEBS and Division of Food Safety and Quality and should be carried out quarterly (KEBS, 2012).

Effective monitoring will ensure that inputs, processes, and outputs with regards to maize flour fortification gives desired outcomes among the maize mills and consequently a great impact in the population on improving their micronutrient health status. Variation in the effects of maize flour fortification in different countries depends on the integrity and quality of the country's surveillance systems (van den Wijngaart et al., 2013). Since assessment of the impact of fortification on micronutrient malnutrition is compromised by supplementation, fortification is aimed at complementing other interventions aimed at reducing micronutrient deficiencies.

Monitoring of maize flour fortification at production and retail level will give an overview of the conformance and stability of the micronutrients on storage.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Design

The study was done in two phases. In the first phase, a cross-sectional study design was used to characterize commercial maize mills and determine the status of flour fortification among these mills. The challenges leading to non-implementation of the program and non-compliance, for those fortifying, and the possible solutions to strengthen the national flour fortification programs were also identified. In the second phase, compliance of commercially fortified maize flour with the set legal standards was determined through analysis of the micronutrients in their most stable forms used during fortification. This involved two components: sampling of maize flour from retail outlets followed by laboratory analysis of the samples to determine the relevant micronutrient levels. The results were then compared to the levels of the legislation requirements at p=0.05 (**Table 2.1**). The retention capacity of the added vitamins was also determined for the entire shelf-life period of flour (6 months)

3.2 Study Site

The survey was carried out among the selected commercial maize mills in Kenya that voluntarily accepted inclusion in the study. Fortified maize flour compliance study was carried out for flour brands from commercial mills within Nairobi/Central and Coastal regions. Freshly fortified flour was obtained from a commercial mill in Nairobi region for vitamin stability tests.

3.3 Study Period

The industry survey for characterizing the commercial maize mills and determining the status of flour fortification was carried out in October and December 2017 while compliance analysis was carried out between May and August 2018. The vitamin stability analysis was carried out monthly for a period of six months from July to December 2018.

3.4 Sampling

3.5.1 Sampling Procedures for Data Collection among the Commercial Maize Mills in Kenya

A representative sample size of commercial maize mills was obtained from the published tables were from a population of 150 commercial mills (Masoud, 2013)) and 90% confidence level, the minimum sample was supposed to be 64 (Israel, 1992). The mills were selected using a stratified purposive sampling technique.

The country, Kenya, was stratified into 6 regions (Nairobi and Central, Eastern and North-Eastern region, Coast region, North Rift, South Rift, and Nyanza and Western regions). These regions were derived geographically from the former 8 provinces of Kenya (**Figure 3.1).** However, some of the provinces were clustered together to make a single region for ease of planning for sampling. Nairobi and Central provinces were clustered to make Nairobi/Central region while Western and Nyanza provinces were clustered to make the Western/Nyanza region. Eastern and North Eastern provinces were clustered together based on the fact that the two provinces are arid and semi-arid thus are sparsely populated (Gok & KNBS, 2017).

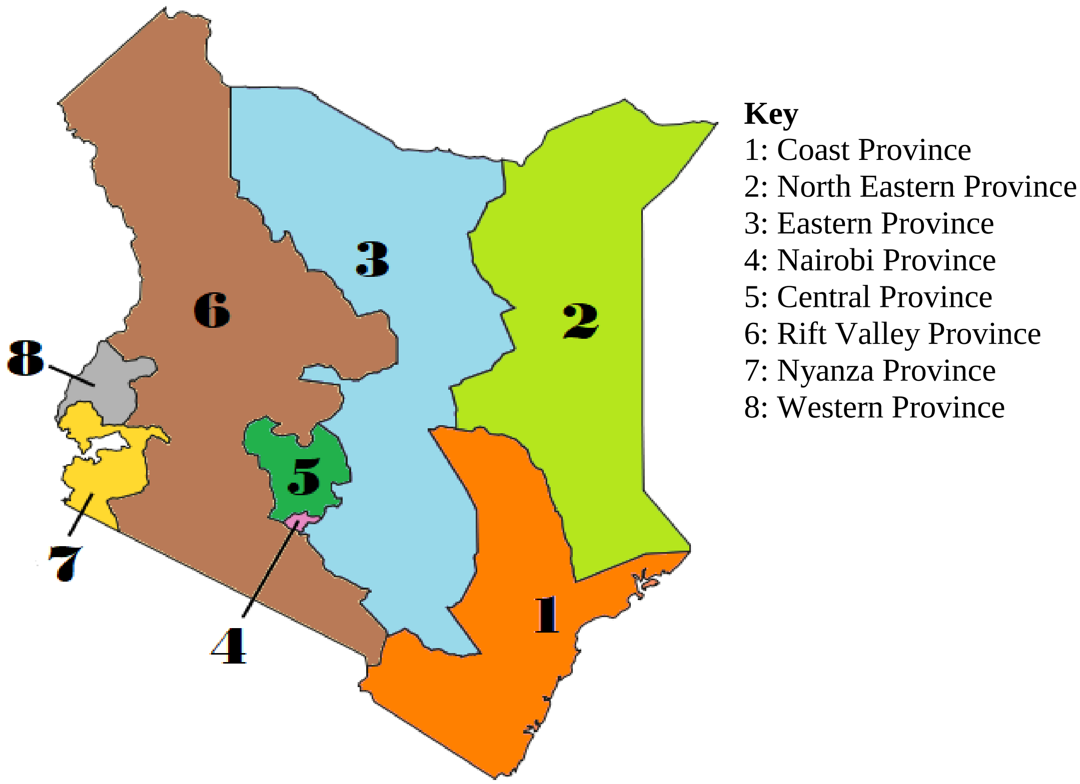


Figure 3.1: Map of Kenya with the 8 former provinces

Commercial maize mills that produce packaged flour were purposively selected from each of the clusters (regions) (**Appendix 1**). Within the Coast region and Western/Nyanza region, mills were sampled by census since these regions were dominated by the small scale mills (Fiedler *et al.*, 2014; Makhumula *et al.*, 2014). The study involved a multistage sampling where commercial mills constituted the secondary sampling unit while the study respondents (company managers, millers and quality control personnel) were the primary sampling units.

3.5.2 Sample Sourcing for Compliance Analysis

From the industry survey, commercial maize mills that had implemented flour fortification programs were identified and their dispersion determined. Two regions, from different climatic zones, were then selected based on the percent proportion of mills fortifying, milling capacities and their high consumer reliance on commercially milled maize flour. These regions were Nairobi/ Central region and the Coast region. Fortified maize flour brands from the mills within the selected regions were identified and sampled at retail points for compliance status analysis. Sampling was done in a manner representative of the consumption patterns of the flour.

Information gathered during sample collection included; date of sampling, sample source, name and address of mill, brand name, sample code, sample manufacture and expiry dates (**Appendix II**). The samples were then transported to JKUAT for analysis.

3.5.3 Sample Sourcing for Vitamin Stability Analysis

One commercial maize mill within Nairobi/ Central region that had implemented flour fortification was randomly selected. From this mill, 7 packages of 2kg each of fresh fortified sample of maize flour was sampled at the point of production and transported to JKUAT for the vitamin stability study.

3.6 Data Collection on Maize Milling Industry Characteristics, Status of Flour Fortification and Key Challenges for Implementation and Sustenance of Flour Fortification Programs in Kenya

Data from the maize mills were collected using structured questionnaires (**Appendix III**). Before the survey, the questionnaire was pretested to ensure clarity, logical flow and appropriateness of the questions used. This was done in 2 commercial maize mills located at Thika and Juja towns, respectively. Simple language was maintained to allow respondents to understand and respond accordingly. Data was collected in paper forms.

This was done by trained researchers from the School of Food and Nutritional Sciences, JKUAT. The questionnaire was split into sections to obtain information on the characteristics of the mills, food fortification practice, quality assurance system, and the level of knowledge of the mill personnel. The target respondents for this study were company managers, millers and quality control personnel. This was based on the assumption that they were well versed in the mill operations and fortification aspects. Data quality was checked interactively for consistency during data entry.

The geographical distribution of the commercial maize mills sampled from the different clusters/region and the sampling schemes applied in each region and the time frame within which data was collected is as shown in **Table 3.1.**

Table 3.1: Sampling schemes per region and the proportion of mills surveyed from the specific regions

S.No	Region	Data Collection Period	Sampling Scheme	Sample Size
1	Nairobi/Central	2^{nd}-6^{th} Oct 2017	Random	28
2	Eastern/North-Eastern	16^{th}-20^{th} Oct 2017	Random	21
3	Western/Nyanza	4^{th}-8^{th} Dec 2017	Census	3
4	Coast	4^{th}-8^{th} Dec 2017	Census	6
5	South Rift	4^{th}-8^{th} Dec 2017	Census	13
6	North Rift	4^{th}-8^{th} Dec 2017	Census	7

3.7 Data Collection on Compliance and Stability of Micronutrients in Fortified Maize Flour Brands

3.7.1 Sample Handling for Maize Flour Compliance Study

The samples were removed from the original packaging and packed in brown khaki bags and labeled using the sample codes in triplicate. This was meant to mimic the normal flour packaging conditions. Conditioning of the samples was then done at 25ºC and relative humidity of 60% using saturated sodium bromide solution for 72 hours before analysis (Kuong et al., 2016). The treatments were meant to remove any variability that may cause differences in the micronutrient contents of the flours. One of the samples was used for the micronutrient analysis while the remaining two were stored in the cold room at 4ºC as reference samples. Low-temperature storage of reference samples was to increase vitamin retention capacity in the flour. The samples were analyzed at 11.8±0.05% moisture content.

Vitamin analysis was done for the most stable form of each vitamin used for fortification. These were riboflavin, nicotinamide, folic acid and retinyl palmitate for vitamin B_2, vitamin B_3, folic acid and retinol respectively. Zinc and iron were analyzed as total ash.

3.7.2 Sample Handling for the Vitamin Stability Study

The fresh sample was removed from the original packaging and packed in brown khaki bags and labeled using different sample codes in triplicate. The fresh samples were labeled and conditioned at 25ºC/RH 60% and 35°C/RH 75% for 72 hours, in their traditional packaging khaki bags, after which a sample for analysis at Time 0 for both conditions were drawn. The conditions for 25^0C/RH 60% were achieved using a saturated sodium bromide solution and 35^0C/RH 75% using a saturated sodium chloride solution.

Micronutrient retention was analyzed under the conditions usually encountered at retail shops and warehouses that are 25ºC at a humidity of 60% in Nairobi and 35ºC at a humidity of 75% in the Coast (Kuong et al., 2016). Micronutrient contents (riboflavin, nicotinamide, folic acid and retinol) were analyzed at baseline (0) and then monthly between 1-6 months for the two storage conditions.

3.7.3 Sample Analysis for Compliance and Vitamin Stability Tests

3.7.3.1 Determination of Vitamin A (Retinyl Palmitate) Content by High-Performance Liquid Chromatography (HPLC)

Vitamin A as retinol was determined according to Zahar and Smith, 1990 with modifications. To 50 ml centrifuge tubes, 2 g of accurately weighed added. Then 5 ml absolute ethanol (Sigma Aldrich) containing 0.1 % ascorbic acid (w/v) (Sigma Aldrich) was then added followed by 2 ml of 50 % KOH (w/v) (Loba Chemie). The tubes were stoppered and agitated then put in a water bath (Memmert WNB 221.230 V-50/60 HZ, F-Nr.: L517.0834) at 80 ºC for 20 minutes. Tubes were agitated periodically to ensure complete fat digestion. After saponification, the tubes were cooled with running water and then placed in an ice-water bath. Approximately 20 ml of hexane (Loba Chemie) containing 0.01 % BHT was added. The tubes were stoppered and vortexed for I minute, allow standing for 2 minutes then vortexed again for 1 minute. Approximately 5 ml of cold water (1ºC) was added, tubes inverted 10 times then centrifuged at 1000 rpm for 10 minutes. Then 10 ml of the upper organic layer was accurately pipetted into rotary flasks and evaporated under vacuum at 40 ºC using a rotary evaporator (Bibby rotary evaporator RE100, water bath RE100B). The residue was dissolved in 1ml methanol and filtered through 0.45 µm Acrodisc® PSF syringe filters (PALL). Analysis of the samples was done using Reverse-phase HPLC (Shimadzu LC-20 A, Japan). The column eluate was monitored with a PDA (SPD-M20 A) at 325 nm (Zahar, M., & Smith, 1990).

3.7.3.2 Determination of Vitamin B_2 (Riboflavin) Content by HPLC

Flour samples were prepared for riboflavin analysis according to Rashid and Potts, 1980 with modifications. About 5g of the sample was accurately weighed in triplicate into centrifuge tubes, labeled and diluted with 20 ml of 2% acetic acid (Sigma- Aldrich) solution. The sample was vortexed (IWAKI mixer, model-TM-151, no. 68130) for 2 minutes and left to stand for 1 minute and vortexed again for 2 minutes. The samples were then centrifuged (Hettich Zentrifugen, D-78532 Tuttlingen, Germany) at 10000 rpm for 20 minutes. The supernatant was filtered through 0.45 µm Acrodisc® PSF syringe filters (PALL). Analysis of the samples was done using Reverse-phase HPLC (Shimadzu LC-20 A, Japan). The column eluate was monitored with a photodiode array detector (SPD-M20 A) at 266 nm (Rashid & Potts, 1980).

3.7.3.3 Determination of Vitamin B_3 (Nicotinamide) and Vitamin B_9 (Folic Acid) Content by HPLC

Determination of vitamin B3 (nicotinamide) and B9 (folic acid) was done according to Ekinci and Kadaka, 2015 with slight modifications. About 5 g of the flour sample was accurately weighed into centrifuge tubes in triplicate and labeled. Then 20 ml of acidified deionized water was added and vortexed (IWAKI mixer, model-TM-151, no. 68130) for 2 minutes. The mixture was then centrifuged (Hettich Zentrifugen, D-78532 Tuttlingen, Germany) at 10000 rpm for 10 minutes. The supernatant was carefully removed and filtered through 0.45 µm Acrodisc® PSF syringe filters (PALL). Analysis of the samples was done using Reverse-phase HPLC (Shimadzu LC-20A, Japan). The column eluate was monitored with a PDA (SPD-M20A) at 282 nm for folic acid and 261 nm for nicotinamide (Ekinci & Kadakal, 2005).

3.7.3.4 Determination of iron and zinc contents by Atomic Absorption Spectroscopy

Total zinc and iron contents in the flour samples were determined by ashing as described by AOAC, 2000. About 2 g of the flour sample was accurately weighed in triplicate and ashed for 5 hours in an Advantee KL-420 electric muffle furnace at 550 ^{O}C. The ash was diluted to 100 ml using 1N HCl (Sigma Aldrich) and filtered through Whatman's No.1 filter paper before analysis using A Shimadzu model atomic absorption spectrometer (Japan).

3.8 Data Analysis

Data for the survey were analyzed using the Statistical Package for Social Sciences Version 23.0 (SPSS). Commercial maize mills surveyed were categorized based on their respective daily milling capacities as described by Enzama (2017), where mills producing over 50 metric tons (MT) per day of maize flour were considered large scale, those producing between 20 MT and 50 MT/day were medium-scale while those producing below 20 MT per day were small scale (Enzama, Roff wwwroffcoza, et al., 2017).

The chemically analyzed vitamins and minerals were entered into Microsoft Excel 2010 and the means and standard deviations calculated. The mean retinyl palmitate (vitamin A), riboflavin (B_2), nicotinamide (B_3), folic acid (B_9), zinc, and iron contents were expressed in parts per million (mg/kg). The micronutrient contents were compared to the fortification levels for maize flour as per the Kenya Bureau of Standards, EAS768 (EAC, 2011).

Vitamin retention values were given as a percentage of the number of micronutrients present in the fresh fortified maize flour compared to the amount of micronutrient present after every month of storage at different storage conditions. Differences in the retention capacity of each micronutrient at different time periods were calculated using analysis of variance (ANOVA), with p-value < 0.05 considered statistically significant. Data were analyzed using Genstat statistical package 12th edition, 2009 (VSN International, UK).

3.9 Ethical Consideration

Permission to conduct the study was obtained from the Ministry of Health, Kenya and the Board of Postgraduate Studies, JKUAT

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Maize Milling Industry Characteristics and the Status of Flour Fortification in Kenya

4.1.1 Characteristics of the Commercial Maize Milling Industry in Kenya

4.1.1.1 Maize Mills' Distribution and Characteristics of the Respondents Interviewed

A total of 78 mills were covered in the study from the six regions of Kenya (**Figure 3.1**). This was above the minimum sample size of 64 mills. The highest proportion of the mills (35.9%) were in the Nairobi-Central region. This is because this region has over 7.5 billion people most of who depend on commercially milled maize flour (Kenya National Bureau of Statistics (KNBS); ORC Macro, 2010; Muyanga, Jayne, Argwings-Godhek, & Joshua, 2006). The Rift valley region (North and South Rift regions) accounted for 25.7% of the respondents as most of the maize in Kenya is produced within this region (Ngeno. et al., 2011), Eastern and North Eastern accounted for 26.9% of the respondents while the coastal region, Nyanza and Western accounted for 7.6% and 3.8% of the total mills, respectively. Nyanza/Western region had the lowest proportion of commercial mills because this region is dominated by retail mills. Most of the inhabitants of the Nyanza/ Western region are small scale farmers who prefer to mill their flour in the retail/ posho mills (Muyanga et al, 2006). The highest proportion (46%) of respondents were company directors while 23.6% was the company managers. The other respondents were millers and quality control personnel.

4.1.1.2 Classification of the Maize Mills

Daily milling capacities were used to classify the mills (Enzama, Afidra, et al., 2017). A total of 22 mills (28.2%) were producing over 50 MT/day of maize flour thus were considered large scale, 25 mills (32.1%) were producing between 20 MT and 50 MT/day thus considered medium scale, and 31 mills (39.7%) were producing below 20 MT per day thus were grouped as small-scale **(Table 4.1).**

Table 4.1: Characteristics of commercial maize milling industry structure in Kenya

Characteristics		Small-Scale Mills	Medium-Scale Mills	Large-Scale Mills
Number of mills surveyed		31	25	22
Number of employee	Range	3-40	8-98	17-600
	Mean ± S.E	14±2	29±5	185±44
Milling technologies used	Roller mill	85.7%	95.8%	100%
	Hammer mill	14.3%	4.2%	
Installed milling capacity (MT/day)	Mean ± S.E	26.1± 5.1	47.5±7.1	172.8±32
	Range	1.9-144	19.9-192	48-600
Actual milling capacity (MT/day)	Mean ± S.E	9.26 ±1.2	32±1.81	148±26.8
	Range	0.1-19.2	24-49.9	55.2-500

Most of the mills were not operating at full capacity (81.3%). The total amount of flour produced by all the sampled mills was 4629 MT/day out of their possible installed capacity of 6084 MT/day. This represented an average daily production of 76% of the available capacity. This is similar to South Africa milling actual daily milling of 79.5%

(Abu & Kirsten, 2009). This indicated that mills were idle 24% of the time. The mills had a short supply of maize following maize shortage that had hit the country due to post-harvest losses and below-average harvest (Oino, Sorre, & Kareithi, 2017). Some of the causes of post-harvest losses were as a result of rodents and poor handling. Poor handling of maize flour led to growth of molds causing contamination by aflatoxin, a toxin produced by fungi due to exposure to moisture (Flanders et al., 2011; Ngeno. et al., 2011).

Large-scale mills accounted for over three-quarters (76.2%) of the total maize flour (MT) produced daily. This was slightly higher than the earlier reports where large-scale mills accounted for about 66% of the flour in the Kenyan market (USAID, 2010). The dominance of large scale mills in the Kenyan milling industry provides an opportunity to supply fortified flour to a larger population group. Large scale mills enjoy economies of scale in fortification thus low losses incurred in the implementation of fortification programs (Fiedler et al., 2014; Makhumula et al., 2014). The technology employed for milling varied with each category of mills but the processing steps were similar. Generally, the milling process involved the following steps: dehulling, degerming, milling and packaging of the flour. It was observed that the mills applied roller and hammer milling technologies. This resonates with the earlier findings of Fiedler et al. (2014) that roller and hammer milling technologies were used in maize milling. Roller milling accounted for over 93% of the milling technology used. All the large-scale mills (100%) used roller milling technology, while the technology was employed at a slightly lower rate of 96 and 85% in the medium and small-scale mills, respectively (**Table 4.1**). The preference of roller to hammer milling in Kenya is similar to the context of Zambia and Uganda maize milling (Fiedler et al., 2014). Hammer mills are simple and use small-scale technology that produces high extraction maize flour while roller mills are large and use advanced technology in milling. The feasibility of fortification in roller mills is higher compared to small scale mills that have a small out output levels making high incremental costs for the adoption of fortification in routine milling (Fiedler et al., 2014; Seleka, Jackson, Batsetswe, & Kebakile, 2011). Roller milling technology allows for ease of adoption fortification as part of the routine milling process.

4.1.1.3 Flour Packaging

Some mills had automated packaging of flour while others had manual packaging. Over 97% of the mills packaged their flour in Kraft papers of 1-2 kg, 46% packaged in sacks while approximately 43% of the mills packaged in both sacks and Kraft papers. Flour packaging is important in the interaction of nutrients with the environment (Hemery et al., 2017). In cases of fortified flours, packages that are permeable to oxygen (sacks) may lead to a reduction of the retention capacity of added vitamins. Mills should use packages that minimize exposure to some environmental conditions including heat, light, oxygen, humidity, and alkaline/acidic environment (Dunn et al., 2014; Kuong et al., 2016)

4.1.1.4 Employment Levels and Labour Type

The Kenya commercial maize milling industry provide employment to the Kenyan population. Small-scale mills employed an average of 14 employees ranging from 3 to 40 employees per mill. Over half (54 %) of the employees among small-scale mills were male. The mean number of employees among medium-scale mills was 29 and it ranged from 8 to 98 persons. There was gender parity at the medium scale level. On the other hand, large-scale mills had an average of 185 employees. The number of male employees was double that of women for large-scale mills (**Table 4.1**). Large scale mills had higher proportion of employees as compared to the medium and small scale mills as the mill is relatively huge.

4.1.1.5 Skilled Labour

The employees in the maize milling industries comprised both skilled and unskilled labour (**Table 4.2**). It was observed that skilled labour was limited to certain aspects of the milling process including miller operation, quality control, and administration while cleaning, packaging, and loading were carried out by non-skilled labour. Most of the mills (7%) had less than 20% skilled labour. Most of the skilled labour was found in large-scale industries. The presence of skilled labour in the milling industry is an important consideration for the implementation of flour fortification. Training gaps in all aspects of fortification including fortification standards, premix handling and storage, doser operation, calibration and maintenance, and quality assurance practices can easily be addressed with a skilled workforce (Allen et al., 2006; Peña-Rosas et al., 2014).

Table 4.2: Proportion of skilled labour in commercial maize mills

The proportion of skilled labour (%) in commercial maize milling	**Number of mills**
<10	31
11-20	24
21-40	10
41-60	6
61-80	3
81-90	2
91-100	2
Total	**78**

4.1.1.6 Quality Assurance Practices by Commercial Maize Mills

Less than one third (30%) of the maize mills had a laboratory for quality assessment and 28.6% had documented guidelines on quality control. Quality control practices are important in assuring the quality and safety of the products for the consumers (Sablah, Grant, & Fiedler, 2013). Low capacity of the mills to carry out quality control during maize milling and flour fortification indicates that the flour to be produced may be unsafe and noncompliance with the statutory regulations for food production.

a) Maize grain quality parameters

Maize grain quality was considered by the mill before purchase for milling. Some of the important quality parameters highlighted by the mills were moisture content, color, foreign materials, aflatoxin, and broken grains. All the mills confirmed checking the maize moisture content. Over four-fifths, (84.6%) of the mills checked maize color and the presence of foreign materials (85.5%) before buying (**Figure 4.1**). The recommended moisture content for maize before purchase is 12% -13 % (Weinberg et al., 2008).

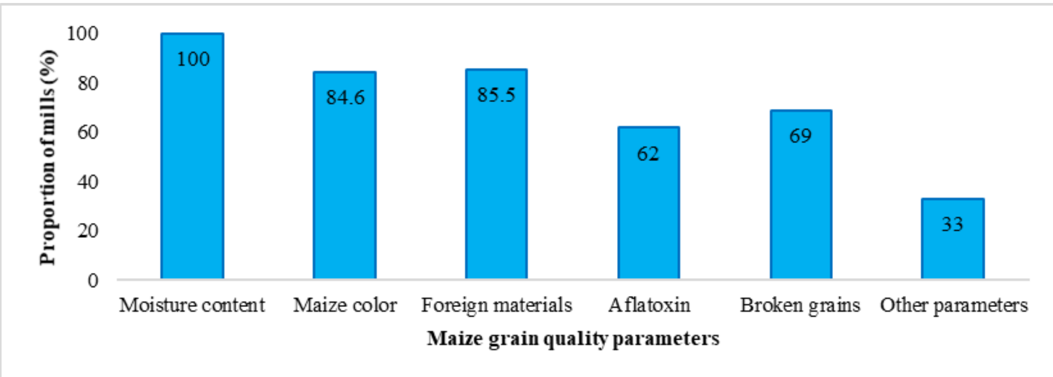


Figure 4.1: Maize grain quality parameters monitored by the mills

b) Maize flour quality parameters

The routine quality tests conducted by the mills for inspecting maize flour included moisture analysis, aflatoxin analysis, and maize physical appearance (**Table 4.3**). The most common routine test carried out among most mills (88%) for flour was moisture determination. This is due to the negative impact of high moisture on the product. High moisture supports mold growth that renders the flour unpalatable (Bothast, Warner, & Kwolek, 1981).

Aflatoxin testing was done by 36% of the respondents. Maize flour has been implicated in aflatoxin poisoning resulting from mold contamination of maize in the farm or in storage. Ensuring aflatoxin levels in flour below 20 parts per billion (ppb) assures the safety of the product to consumers (Flanders et al., 2011). The fineness of the flour grains, the color of the flour and moisture content of the flour are important quality parameters that should be monitored frequently (Makhumula et al., 2014).

Table 4.3: Maize flour routine tests carried out by maize mills

Maize flour routine tests in maize mills	No of mills	The proportion of mills carrying out routine tests (%)
Micronutrients test including iron spot tests and dosing amounts monitoring	5	10
Sensory tests that involve the preparation of food from the products and tasting	8	16
Moisture analysis	44	88
Aflatoxin analysis	18	36
Physical appearance including flour color, flour particle size/texture, weight on the packaging, flour odor	24	48
Foreign materials including impurities and pest residues	6	12
Proximate composition and microbial test	8	16

The frequency of internal monitoring of maize flour among the mills varied greatly among the mills. The practice varied from hourly checks to daily checks or even batch assessments. Over half of the companies (53 %) carried out internal monitoring tests on every batch (**Figure 4.2**).

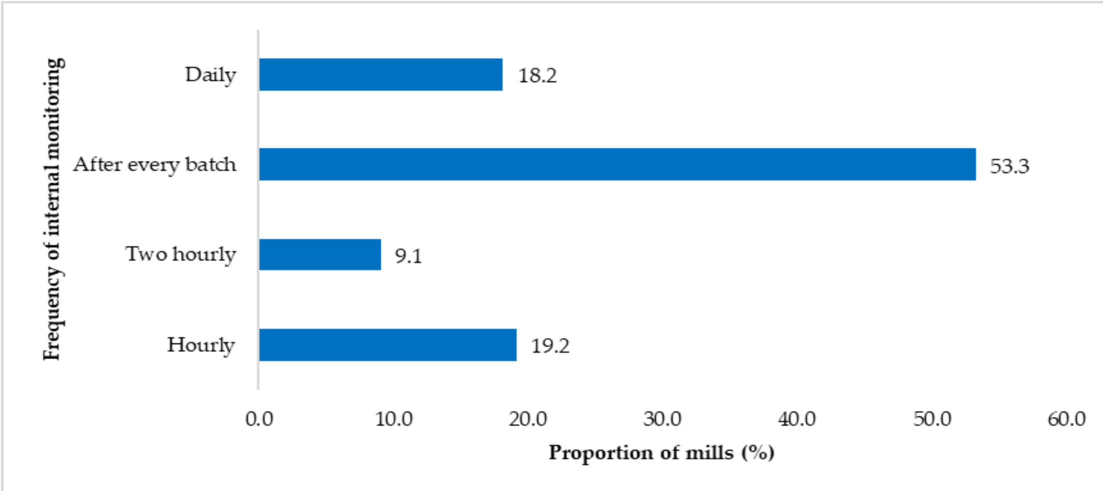


Figure 4.2: Frequency of internal monitoring among commercial maize mills

4.1.1.7 Quality Assurance Practices by Regulatory Bodies

Over 95% of the mills had their maize flour samples tested in external laboratories including KEBS, Food Safety Unit (Ministry of Health, Kenya), SGS and Polycon International Ltd among others. During external monitoring, aflatoxin (60%) and chemical and microbial (60%) tests were the most common quality parameters checked by the regulatory bodies **(Figure 4.3).**

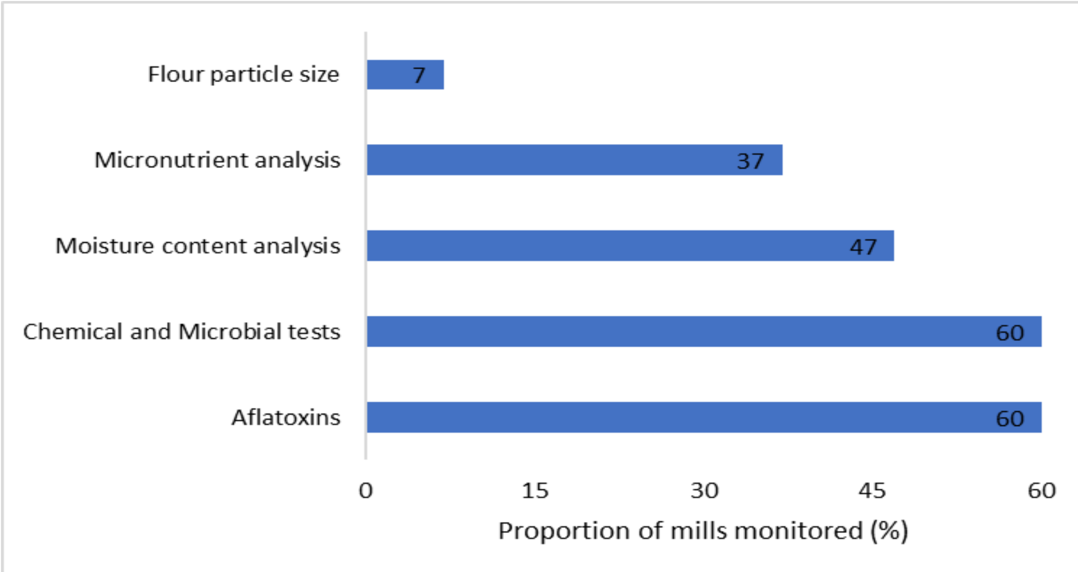


Figure 4.3: Proportion of mills monitored by regulatory bodies for different maize flour parameters

The frequency of external monitoring varied greatly from monthly to annually. Those that carried it out bi-annually and quarterly were 23.8% and 22.2%, respectively. Only 3.2% of the mills subscribed to weekly monitoring of flour (**Figure 4.4).** Regular regulatory monitoring is important in ensuring the integrity of fortification and milling processes to ensure high-quality flour (Luthringer et al., 2015).

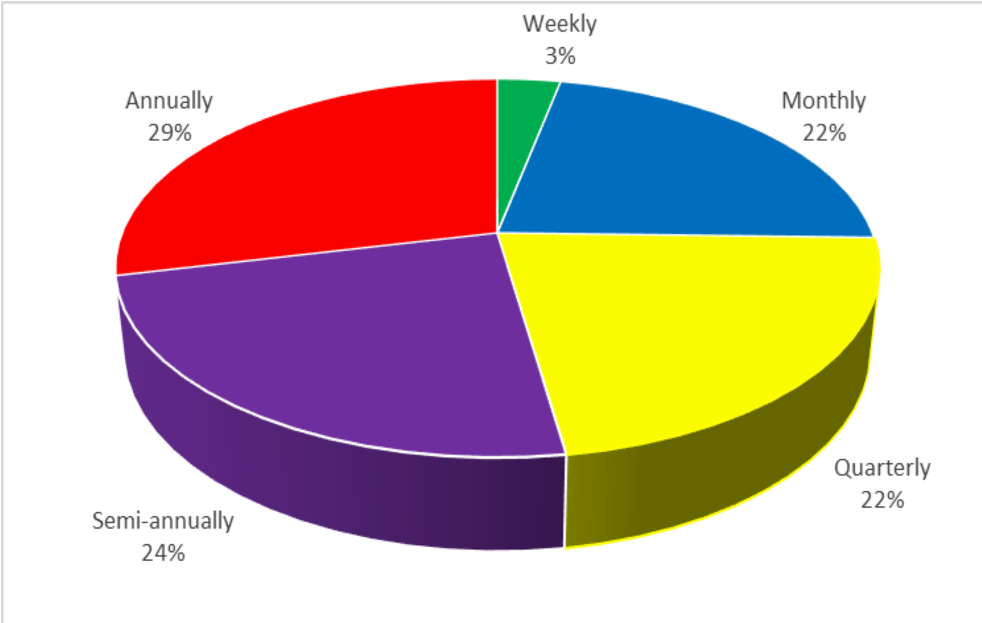


Figure 4.4: Frequency of flour external monitoring

About 39% of the mills perceived the cost of external monitoring to be affordable while 25% were not sure. About a quarter (22.3%) of the mills considered the cost of external monitoring to be high or very high **(Figure 4.5).** High-cost external monitoring limits the frequency at which the mills would seek these services thus compromising the quality of the fortified flour in terms of safety and compliance to the fortification standard (GAIN, 2017; Luthringer et al., 2015)

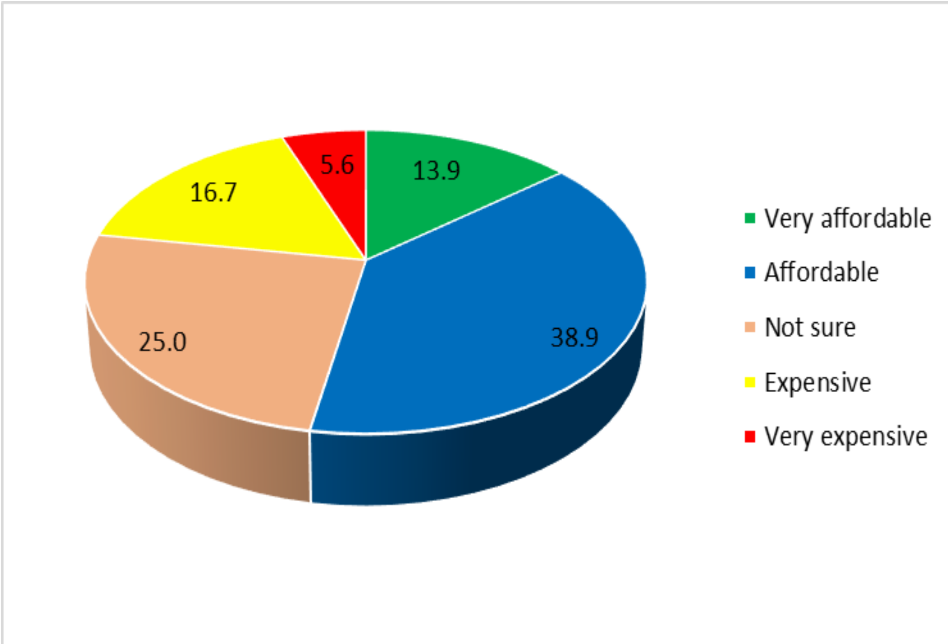


Figure 4.5: Perception of the cost of external monitoring

Regulatory agencies involved in external monitoring of flour were the Kenya Bureau of Standards (KEBS), Ministry of Health (MOH), National Environment Management Authority (NEMA), and Ministry of Trade. The proportion of mills inspected by these regulatory bodies is as shown in **Figure 4.6**. Most of the regulation related issues were handled by MOH and KEBS (> 95%) since they are mandated by the GOK to do so (EAC, 2011).

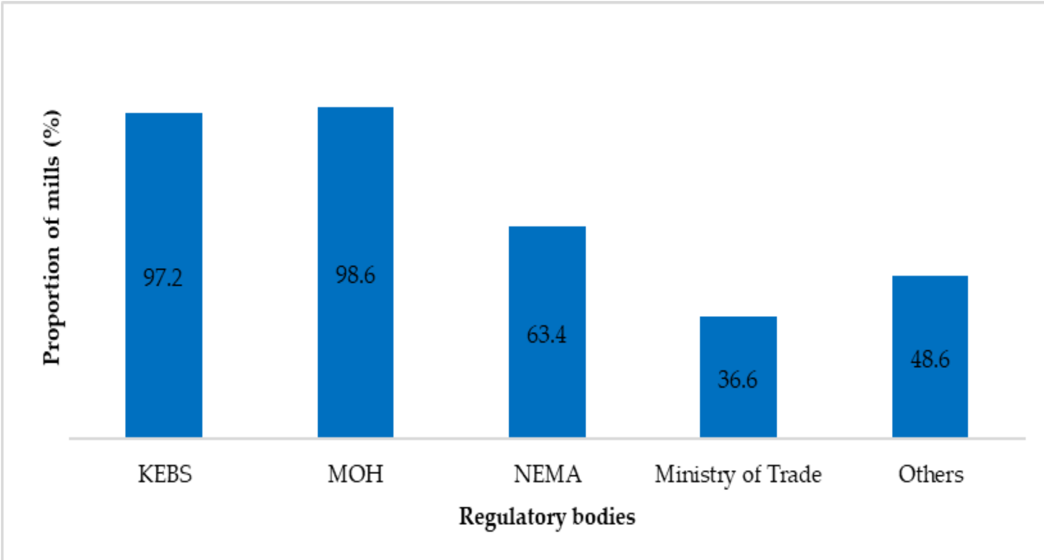


Figure 4.6: Regulatory bodies that had inspected the commercial maize mills

The frequency of monitoring by regulating agencies varied from weekly to annually. KEBS and MOH carried out monthly to quarterly evaluation while NEMA assessed annually (**Figure 4.7**).

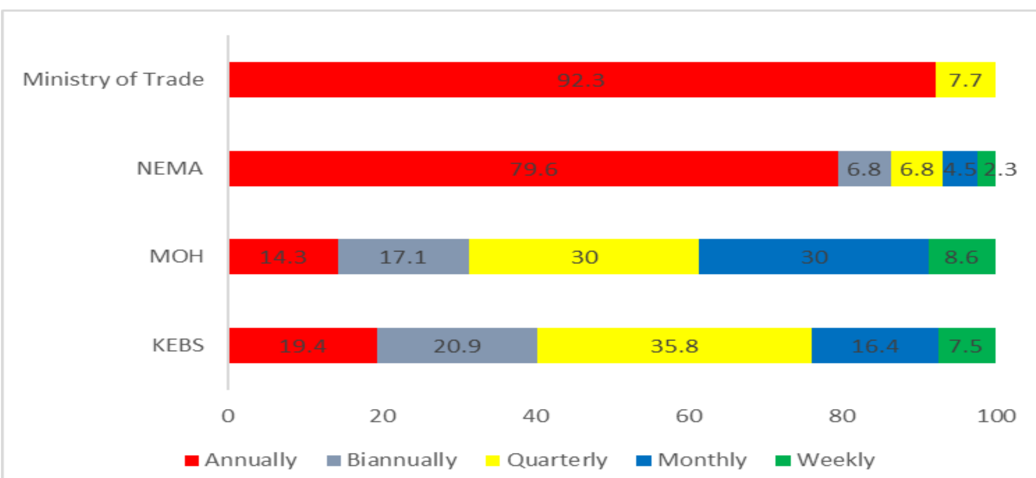


Figure 4.7: Frequency of inspection of commercial maize mills by regulatory bodies

Nearly 97% of the mills reported that they had received feedback from the regulating agencies, though the timelines differed from immediate feedback to 3 to 6 months after inspection (**Figure 4.8**).

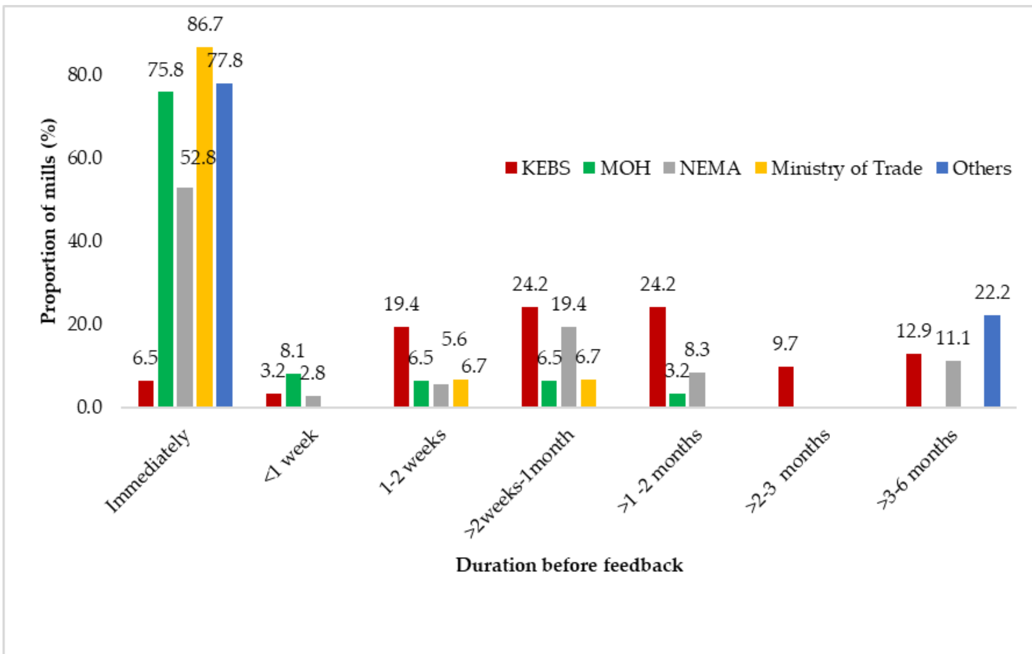


Figure 4.8: Duration before feedback by regulatory bodies

Effective monitoring ensures that inputs, processes, and outputs with regards to maize flour fortification give desired outcomes among the maize millers and consequently a great impact in the population on improving their micronutrient health status (Luthringer et al., 2015).

Capacity building of the companies QA and regulatory bodies in quality management systems is critical. Continuous reinforcement of the company personnel knowledge and skills in fortification is also important for fortification program sustenance. HACCP plans have to be incorporated with QC analytical procedures for micronutrient analysis of fortified foods, sampling plans, record-keeping procedures, premix handling and storage procedures, fortification equipment operation and maintenance procedures (doser calibration) and sanitation standard procedures. This is aimed at ensuring maximum safety and quality of fortified maize flours (Luthringer et al., 2015; Makhumula et al., 2014)

Regulatory bodies have a responsibility to ensure compliance of fortified flour to the set legal standards (KEBS, 2012). This is possible through periodic sampling and analysis of the flour micronutrient levels. Regulatory bodies thus have to be equipped with analytical tools, standard methodologies, and enough trained personnel to carry out its mandate (Makhumula et al., 2014).

4.1.2 Current Practice and Coverage of Maize Flour Fortification in Kenya

4.1.2.1 Maize Flour Brands and Their Distribution in the Market

A total of 101 brands of maize flour were identified from this study **(Appendix II).** About a third of the brands (30.7%) were supplied by large-scale mills while medium and small-scale mills supplied 31 and 39 brands, respectively. Small-scale mills supplied flour within their geographical locality while medium-scale mills supplied mostly within their counties. Most large-scale mills supplied flour to specific regions of the country (63%) while a few supplied countrywide (**Table 4.4**). The range of coverage of flour supply in the country provides an advantage for use as an appropriate food fortification vehicle that can reach the vulnerable groups of the population (Zamora & De-Regil, 2014)

Table 4.4: Status and practice of maize flour fortification in Kenya

Characteristics		Small Scale Mills	Medium Scale Mills	Large Scale Mills
Proportion of mills fortifying (%)		24.1	45.8	100
Proportion of mills using logos (%)	KEBS logo only	58.6	45.8	0
	KEBS + Fortification logos	41.4	54.2	100
Type of packaging used by mills (%)	Sacks	37.9	50	52.6
	Kraft paper/ Khaki	93.1	100	100
	Sacks + Kraft paper	31	50	52.6
Geographical coverage of maize flour products in the market (%)	District	3.4	12.5	0
	County	31	20.8	0
	Region (based on old provinces)	62.1	54.2	63.2
	Country	3.4	12.5	36.8
Distribution of doser brands among mills (%)	Buhler	0	16.7	77.8
	Unspecified Chinese	75	66.7	5.6
	Yilmaz redurkto Turkey	0	8.3	5.6
	Roff	0	0	11.1
	Picture	12.5	0	0
	Fabricated	12.5	8.3	0

4.1.2.2 The Proportion of Mills with Flour Fortification Practice in Place

Over half of the mills (51.39%) surveyed confirmed to have implemented the mandatory food fortification programs for maize flour as required in Kenya. All of the large-scale mills fortified the flour while less than half (45.8%) of the medium scale and a quarter (24.1%) of the small-scale mills did so (**Table 4.4**). The slow adoption of fortification programs by the mills was attributed to the lack of reliable premix suppliers in the market, long premix importation periods, inadequate quality control capacity of the mills and inefficient regulatory monitoring of premix suppliers and commercial maize mills by the mandated regulatory bodies.

To verify whether food fortification was being carried out, the presence of the fortification logo and the standardization mark of quality from Kenya Bureau of Standard, KEBS, were checked on all the flour packages. All mills (100%) confirmed the use of the KEBS logo on their package. However, only 61.1 % of the brands had both KEBS and the food fortification logos. Some mills (10%) were using fortification logos yet they were not fortifying their products. While this is misleading to consumers and regulators, the mills revealed that they were aware of this practice. A further check on why these companies were using the fortification logo without actually fortifying revealed that limited funds to buy premixes, dosers and poor knowledge and skills were the main reasons for the fortification malpractice observed. According to Makhumula, 2014, the imposition of mandatory flour fortification to all the mills risks the collapse of mills that do not have the capacity to fortify (Makhumula et al., 2014)

4.1.2.3 Premixes

a) Premix Supply, Usage, and Storage

Mills that had implemented the mandatory flour fortification programs sourced their premixes from different suppliers. Bio Foods Products limited was the main supplier of premix supplying to a third (32 %) of the maize mills. Other important premix suppliers were High Nutrition Ltd (11.1%), Engrain EA. (9.7%), and Buhler Ltd (8.3%) (**Table 4.5**). All the premix suppliers were located in Nairobi-Kenya, from where they supplied the premixes to the mills countrywide. Premix suppliers play an important role in the sustainability of flour fortification programs by ensuring a reliable premix market for the mills (Allen et al., 2006)

Table 4.5: Premix suppliers in the Kenyan maize milling firms

Premix supplier	No. of mills supplied to	The proportion of mills supplied to (%)
Bio Foods Products LTD	23	31.94
Chemicals and Solvents LTD	1	1.39
Engrain EA	7	9.72
Amesi Kenya LTD	3	4.17
Buhler LTD	6	8.33
High Nutrition LTD	8	11.11
Philips Pharmaceuticals	1	1.39
own importation	1	1.39
others	11	15.28

Premixes were stored under different conditions among the mills. About 69 % of the mills reported storing the premix at room temperature, 25% in a cool dry place while 3% stored in the dark. According to the Food Fortification Initiatives flour millers' toolkit, premixes should be stored away from sunlight, excessive heat, and potential water damage. This is important in maintaining the retention capacity of the micronutrients in the premixes throughout their shelf life (Dunn et al., 2014; Kuong et al., 2016; Luthringer et al., 2015; Stoltzfus et al., 2008).

b) Premix packaging and prices in Kenya

Approximately 93% of the premix was supplied in 25 kg packs, 2.5% in 50 kg, and 2.5% in 100 kg packs and the rest in less than 25 kg packs. Vitamins in the premix have a limited shelf life and overtime their biological activity and effectiveness are reduced

(Dunn et al., 2014). Typically, premixes are packed in polythene bags inside heavy cardboard boxes. Once opened, exposure to light, air, and high temperature has to be minimized to reduce degradation. Poor storage conditions could lead to a reduction in the retention capacity of the vitamin and subsequent non-compliance of flour to standards (Flour fortification initiative, 2008). This was a typical case for vitamins (Luthringer et al., 2015).

The unit price of the premix varied among suppliers but generally ranged from Ksh.500-1500 per kg (**Figure 4.9**).

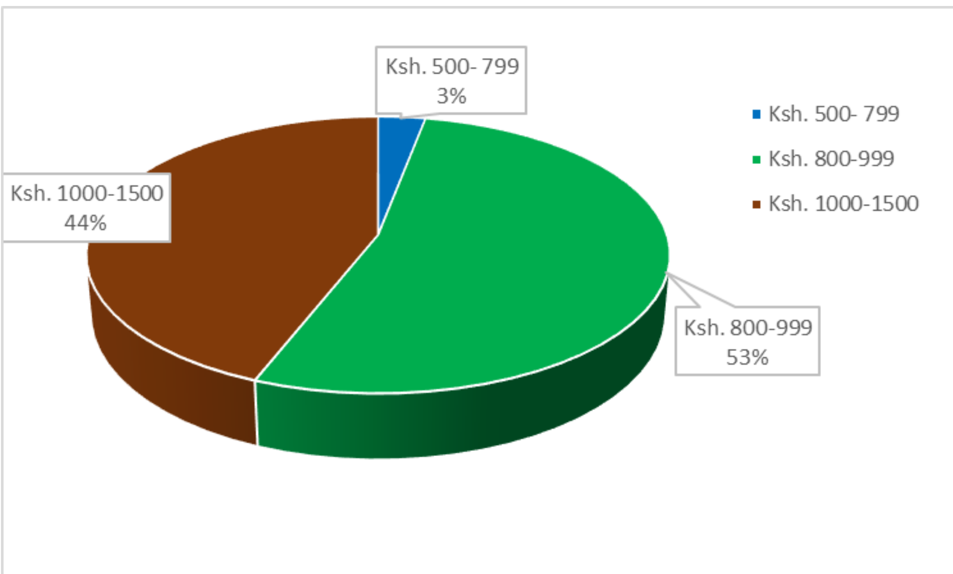


Figure 4.9: Unit prices (Ksh. /kg) for Premixes purchased by commercial maize mills

c) Premix acquisition challenges

There were challenges associated with premix acquisition which varied from one miller to another. Over 60% of the mills had a challenge with accessing the premix on time due to the infrequent supply. Long importation periods from premix manufacturers also contributed to the unavailability of the premix in some mills for some periods. Further, most mills relied on a single premix supplier. Some mills also reported a lack of information on the available certified premix suppliers in the market.

Centralized buying of the premix, for mills that have several milling outlets in the country also presents a challenge to the mills accessing the premix on need due to the bureaucracies that have to be followed before the release of the premix from the headquarter mill to the regional mills. This was a problem reported among centrally managed mills. About half (45%) of the mills in the market perceived the premix to be very expensive. This was particularly a challenge for most of the small scale mills, which despite having acquired dosers were unable to implement fortification for lack of capital to sustain premix acquisition.

The issue of premix quality was another challenge to the mills, as 34% of the maize mills indicated that the premix available to them is of low quality. Some of the mills had no knowledge of how to determine good premix quality in terms of the micronutrients present or reliable premix suppliers.

4.1.2.4 Fortification Equipment (Dosers)

The proportion of mills that were equipped with dosers was 61% of the 78 mills surveyed. Buhler (Kenya) and unspecified Chinese doser brands were the most common and were used by 42.1% and 39.5% of the mills, respectively. Other doser brands used in the mills were Roff-Turkey, Picture-China, and Yilmaz-redurkto-Turkey (**Figure4. 10**). The quality of dosers is important in determining the amount of premix that's released to the flour at a time. Buhler brand was identified as of superior quality as compared to the other brands.

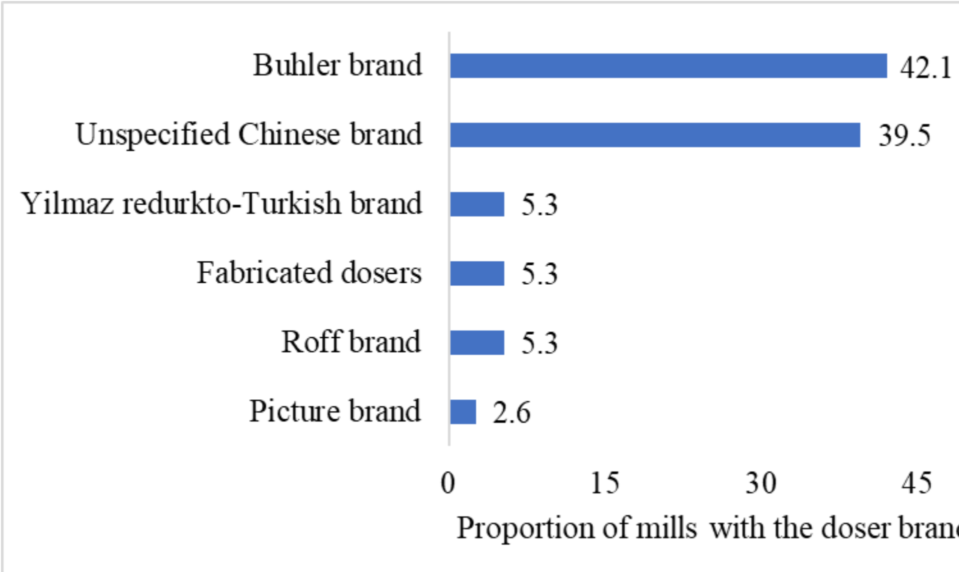


Figure 4.10: Doser brands among commercial maize mills

Over 10% of the mills that had dosers installed had not started fortifying their maize flour. This resonates with the companies that were using the fortification logo but were not fortifying their flour. The high cost and poor quality of dosers were considered the main challenges among small and medium scale mills that contribute to the non-implementation of fortification programs.

The dosers installed were of different sizes depending on the milling capacity of the industry. Over three-quarters of large-scale mills (77.8%) had dosers of over 10 kg capacities. Over half (58.3%) of the medium-scale mills had dosers of capacity above 10 kg while most of the small-scale mills (85.7%) had small, dosers whose capacity was less than 5 kg. Doser capacity determines the amount of premix it can hold at a time and thus efficiency in dispensing the premix into the flour during the milling process.

The cost of the dosers varied depending on their source. Half (50%) of the dosers cost below Ksh.100000 most of which were of Chinese brand (**Figure 4.11**). The cost of dosers relates to doser quality. High cost of quality dosers force millers to acquire cheaper fabricated brands that may not be compatible with their mills. Approximately 10% of the mills that had dosers had not included fortification as part of their routine milling processes. One of the reasons for the delay in implementing the program was due to the poor quality and the incompatibility of the acquired dosers.

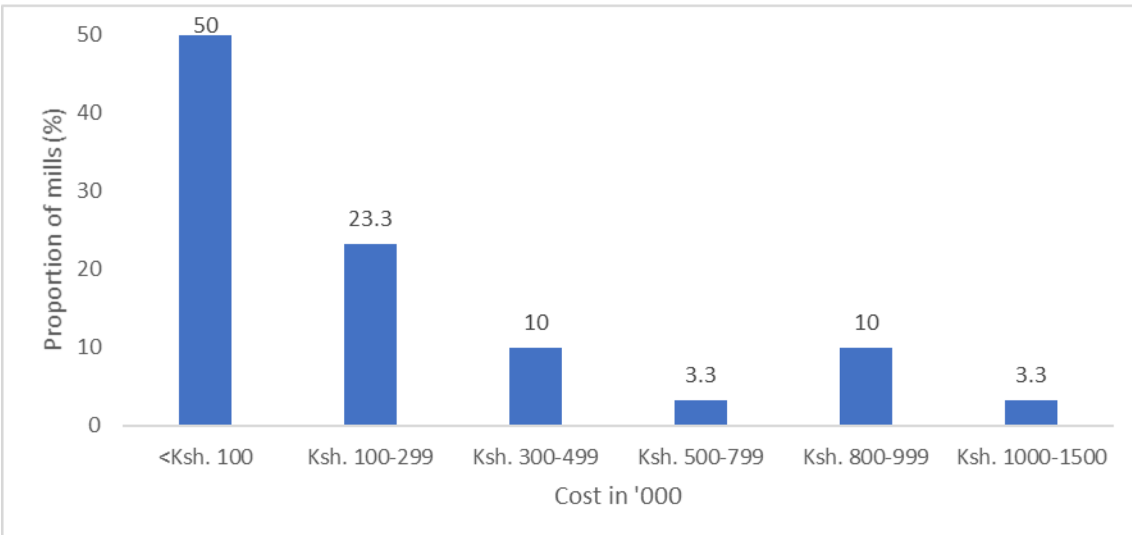


Figure 4.11: Doser costs incurred by maize mills on the acquisition

Most of the dosers (93%) were reportedly compatible with the mills. For high doser efficiency, however, periodic calibration to ensure proper feeder operation within acceptable variation and dispense of accurate amounts of premixes in the flour is required (Johnson et al., 2004; Peña-Rosas et al., 2014). The frequency of calibration for most dosers varied from daily to never. About one-third of the mills (34.9%) reported never to have calibrated their dosers (**Table 4.6**). This raises concern on the effectiveness of fortification (percentage compliance to standards) due to the unregulated dosing.

Table 4.6: Frequency of doser calibration by maize mills

Frequency of Calibration	The proportion of commercial maize mill (%)
Never	34.1
After each batch	7.3
Daily	14.6
Weekly	17.1
Monthly	4.9
Quarterly	4.9
Yearly	2.4
Other	14.6

4.1.2.5 Mixer and /or Mixing Channel

Upon dosing, flour was mixed with the premix for homogeneity. Most (82%) of the dosers were equipped with mixers of different brands. The predominant mixer brand among the mills was Buhler (Kenya) (40%) while unspecified Chinese brands and conveyor belt mixers (Kenya) were in 20% and 15% of the mills, respectively (**Figure 4.12**). Most of the mixers (96.8%) were compatible with their respective mills. Some of the mixer brands were fabricated locally (Buhler, screw mixer, conveyor belt and unbranded fabricated brands) while others were imported from China (Chinese and Zangzous brands)

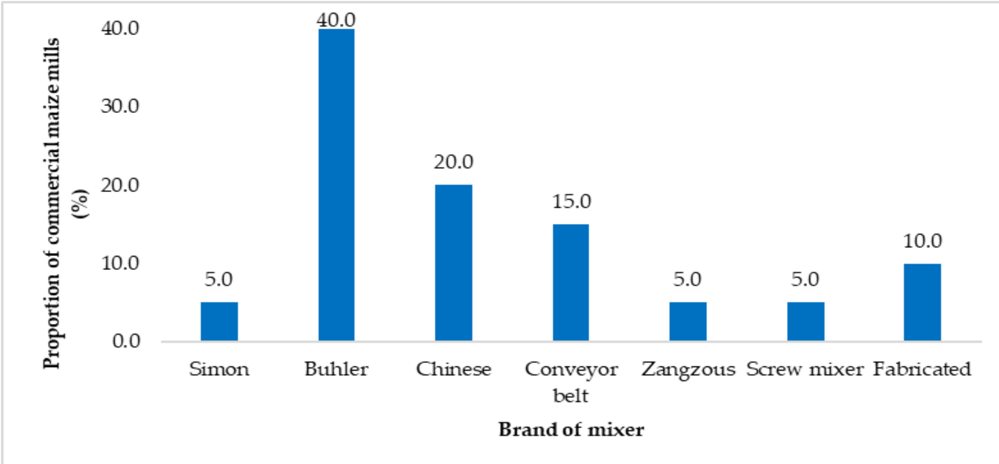


Figure 4.12: Mixer brands among commercial maize mills in Kenya

4.1.2.6 Perception of Fortification on Profits

The perception of the impact of fortification on mills' profits varied from being very high to very low (**Figure 4.13**). Most of the mills considered the cost to be low (41%) with minimal effect on their profits. However, about one-third of the mills (31.5%) stated that fortification significantly affects their profit margins while the rest were not sure of the effects of fortification on their profits. The perception of the impact of fortification on the mills profits determines the willingness of the mills to adopt fortification programs. The incremental costs of fortification, arising from premix, doser and skilled labour acquisition to implement fortification programs, may be too high for small and medium scale mills. On the other hand, due to economies of scale in the large scale mills, such mills can easily adopt fortification as part of their routine milling processes (Makhumula et al., 2014).

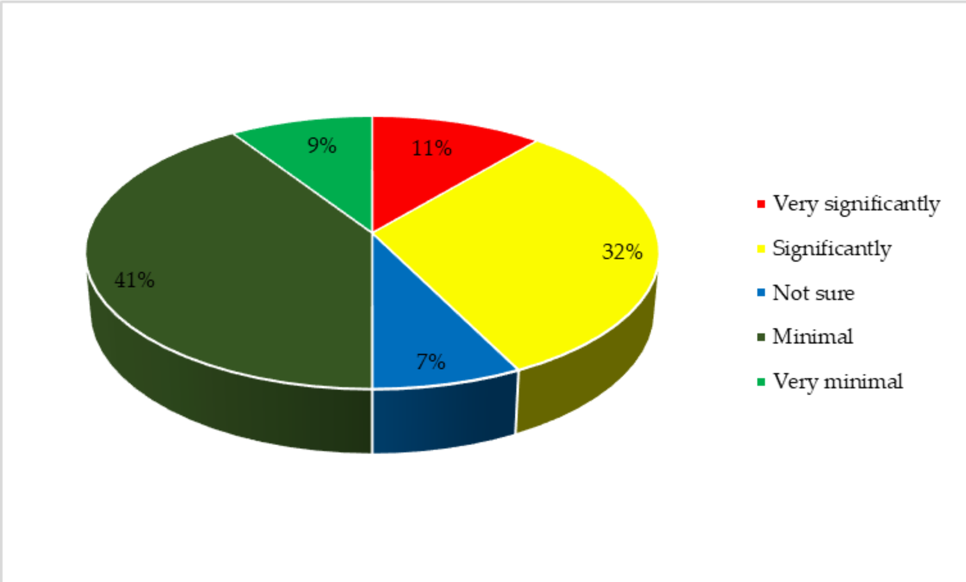


Figure 4.13: Impact of fortification on profits

4.1.3 Training

a) Proportion of skilled labour among the mills

Skilled labour is important in the milling industry as they are involved in such aspects as quality control, mill operation and management. Approximately 90% of the mills had trained mill operators while the rest had no trained mill operator (**Figure 4.16**). The number of trained operators, however, varied with over 85% of the mills having less than 5 trained mill operators (**Figure 4.14**). Presence of skilled in the milling industry makes it easier for adoption and implementation of flour fortification programs.

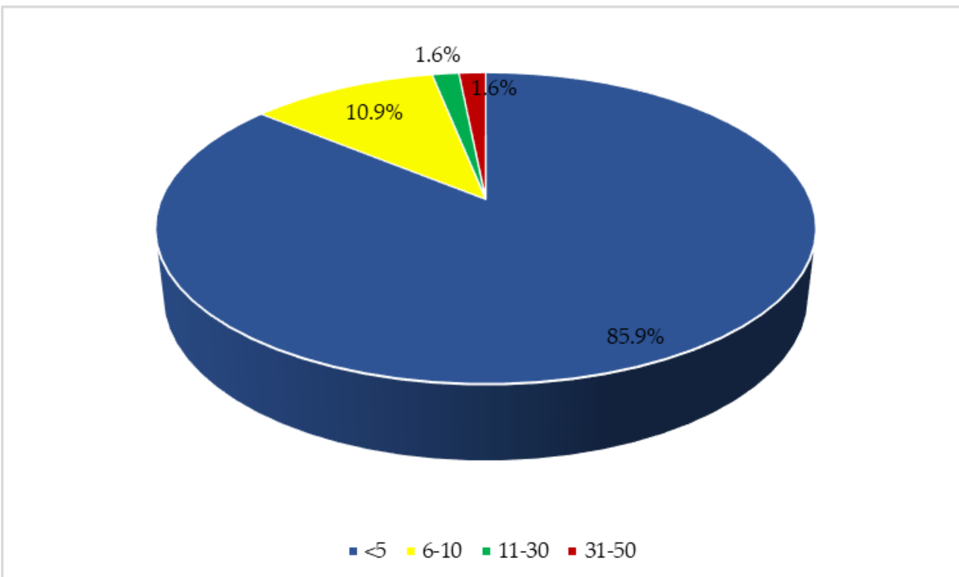


Figure 4.14: Proportion of trained mill operators among commercial maize mills

Most mill operators had undergone on-job training and overtime gained experience to train others. Some mills also organized to have their personnel attend training workshops to gain more skills in milling. However, most small skills mills had mill operators trained in other milling firms. **Table 4.7** indicates the different modes of training by mill operators

Table 4.7: Types of training undertaken by mill operators in the maize milling industries

Type of training	The proportion of commercial maize mills with trained operators (%)
Formal training	23.4
Training workshops	21.9
Supplier training	29.7
Mill-owner training	15.6
On-Job training/ experience	79.7

b) Training on aspects of fortification

Since the amendment of the Kenya Food, Drugs and Substances Act in June 2012 to include the mandatory fortification of specific staple foods by the manufactures in the country, there has been a need for industry personnel to be trained on different aspects of fortification to enable them to implement the programs. Resulting from the requirement on all commercial maize mills to fortify their flour to the set legal standards (KS168/EAS768), there is need for mills to have their operators trained in different aspects of maize flour fortification (**Figure 4.15**) to help them implement maize flour fortification programs and avoid legal action being taken against them.

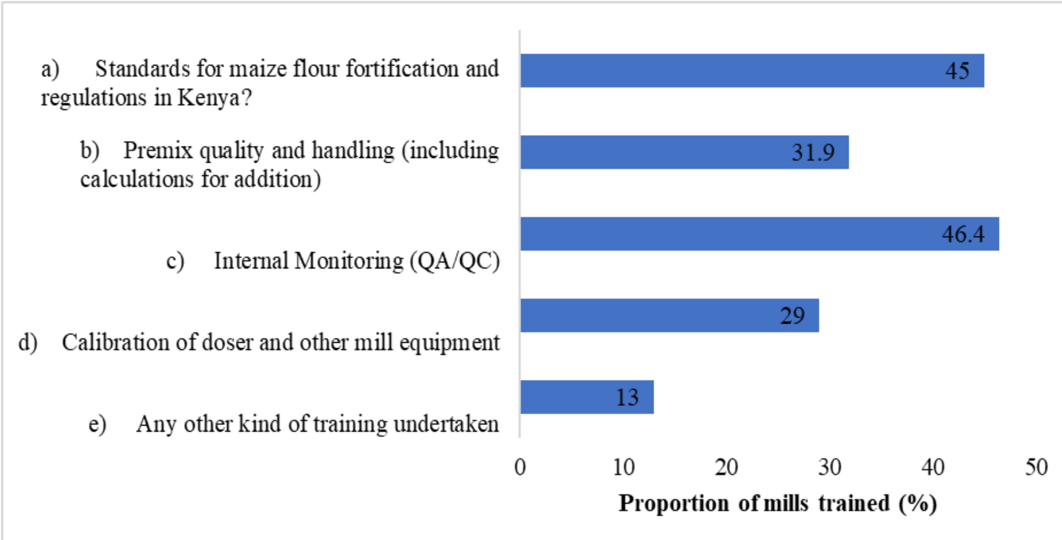


Figure 4.15: Proportion of mills trained in different aspects of fortification

i. Training on standards for maize flour fortification and regulations in Kenya.

About half (45%) of the mills had trained personnel in standards for maize flour fortification and regulations in Kenya. The number of persons trained in this aspect ranged from 1 to 10 persons per mill (**Table 4.8**).

Table 4.8: Proportion of employees trained in standards for maize flour fortification and regulations in Kenya among the mills

Number of persons trained	Number of maize mills with trained personnel	The proportion of mills with trained personnel (%)
1	13	41.9
2	7	22.6
3	3	9.7
4	2	6.5
5	1	3.2
6	4	12.9
10	1	3.2

The training on standards was organized by different organizations among the maize mills. The Kenya Bureau of Standards (KEBS) and the Ministry of Health (MOH) had trained 48.4% and 25.8% of the maize mills in this aspect respectively (**Figure 4.16**).

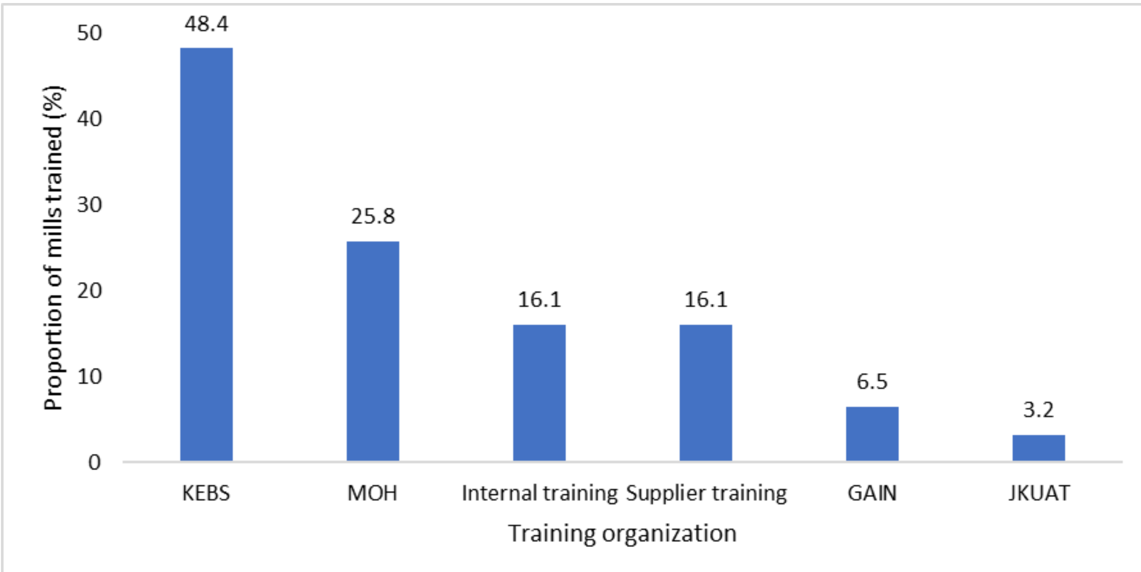


Figure 4.16: Organizations that trained mills in standards for maize flour fortification and regulations in Kenya

ii. Training in premix quality and handling.

About one third (31.9%) of mills had personnel trained in premix quality and handling **(Figure 4.15)**. The number of personnel trained ranged from 1 to 15 persons per mill (**Table 14**).

Table 4.9: Proportion of employees trained in premix quality and handling among the mills

Number of persons trained	Number of maize mills with trained personnel	The proportion of mills with trained personnel (%)
1	6	27.3
2	5	22.7
3	1	4.5
4	3	13.6
5	1	4.5
6	2	9.1
7	1	4.5
10	1	4.5
11	1	4.5
15	1	4.5

The training in premix quality and handling was organized by different organizations as shown in **Figure 4.17.**

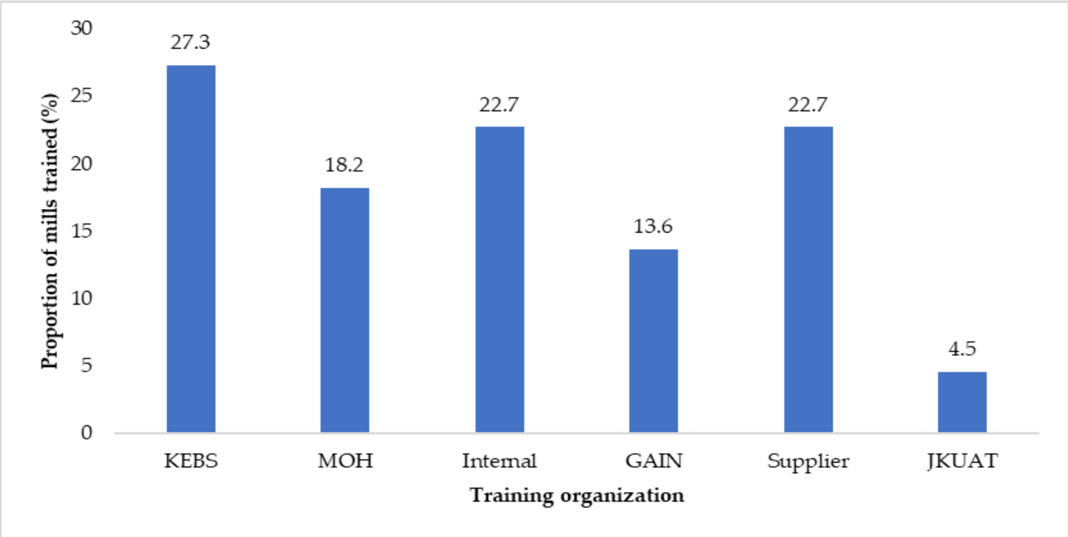


Figure 4.17: Organizations that trained mills in premix quality and handling

iii. Training on internal monitoring.

About half (46.4%) of mills had operators trained in internal monitoring **(Figure 4.15).** The number of personnel trained in this aspect varied from 1 to 10 persons per mill (**Table 4.10).**

Table 4.10: Proportion of employees trained in internal monitoring among the mills

Number of persons trained	Number of maize mills with trained personnel	The proportion of mills with trained personnel (%)
1	12	37.5
2	7	21.9
3	4	12.5
4	5	15.6
6	1	3.1
8	1	3.1
10	2	6.3

The training in Internal Monitoring was organized by different organizations as shown in **Figure 4.18**:

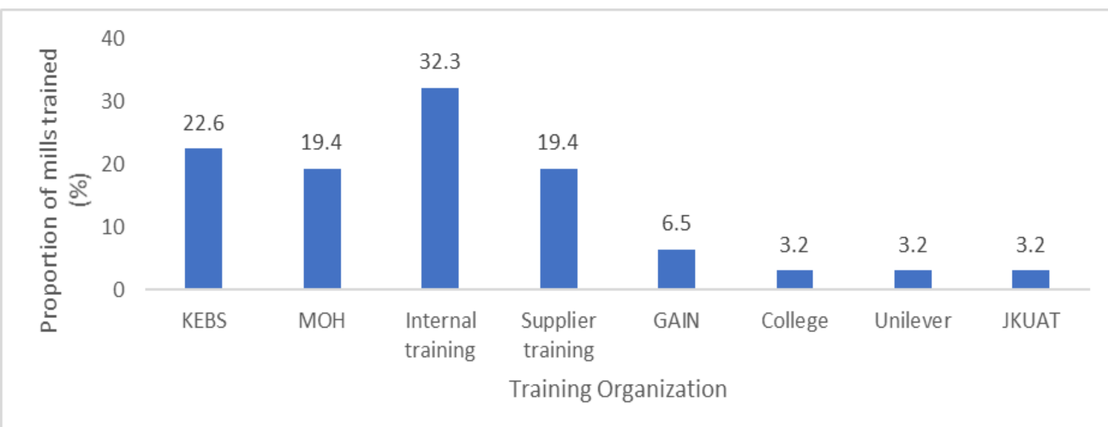


Figure 4.18: Organizations involved in the training of mills in internal monitoring

iv. Training on doser calibration and other mill equipment

About one third (29%) of the mills had personnel trained in Doser calibration and handling of other mill equipment **(Figure 4.15).** The number trained varied from 1 to 10 persons per mill (**Table 4.11**).

Table 4.11: Persons trained in doser calibration and other mill equipment among the mills

Number of persons trained	Number of maize mills with trained personnel	The proportion of mills with trained personnel (%)
1	4	20
2	9	45
3	3	15
4	2	10
7	1	5
10	1	5

The training was mainly provided by the equipment supplier (**Figure 4.19**).

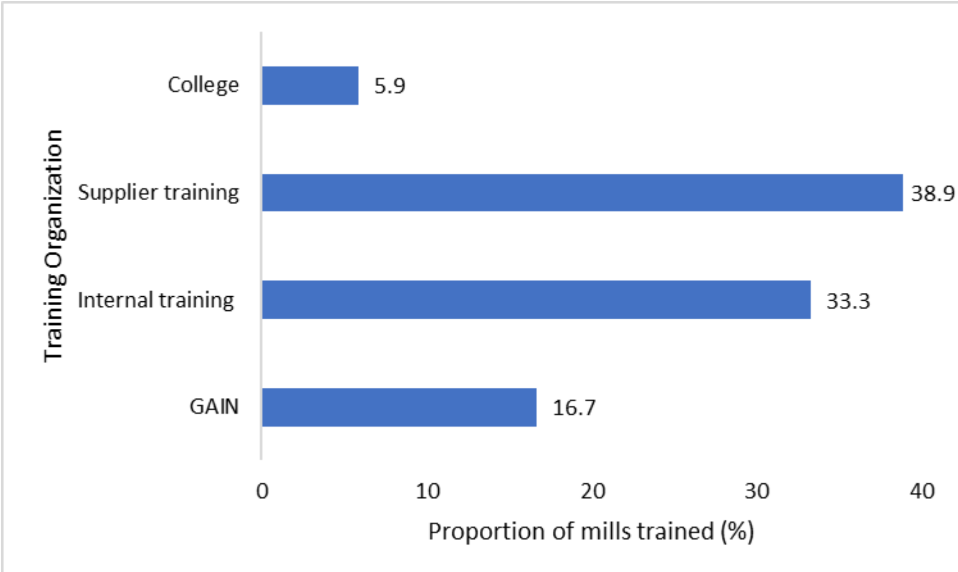


Figure 4.19: Organizations involved in the training of mills in doser calibration and other mill equipment

c) Training gaps

Most (90.5%) of the mills identified that training in all aspects of fortification was important for the implementation and compliance of the fortification requirements of their flour products to the set legal standards. Some aspects most critical to the mills were; premix handling and quality (56.1%), doser installation, operation, and calibration (54.4%) and fortification standards (33.3%).

Sourcing of premixes was also an important aspect of training required by mills, especially with regards to identifying high-quality premixes for purchase and use. The importance of fortification should be taught to the mills and consumers to enhance the success of the program.

About one fifth (19%) of the maize mills required training on aspects of maize milling including mill operation, mill maintenance, grain handling, safety (GMP) and flour packaging. Over half (60.3%) of the mills needed their personnel trained on internal monitoring. The specific aspects identified to be most important were, flour handling, aflatoxin testing in flour and maize, proximate and micronutrient (fortificants) analysis, HACCP, GMP and work ethics.

Bookkeeping is an important aspect of any business. It was observed during the survey that most of the mills do not have documents of feedback from any of the regulatory bodies thus sometimes could not tell what specific aspects are monitored by these organizations. Despite this, only 3.2% of the mills saw a need for training on bookkeeping and documentation

4.2 Key Challenges for Implementing and Sustaining Food Fortification Programs among Commercial Maize Mills in Kenya

A summary of the main challenges during fortification program implementation and practice is given in **Table 4.12.**

Table 4.12: Challenges relating to fortification compliance and proposed solutions

Challenges	Proposed solutions
Lack of access to high-quality dosers at an affordable price (69.6%)	a. Avail high-quality dosers at market friendly prices b. Provide knowledge on how to fabricate dosers locally c. There should be local manufacture of dosers to cut on importation costs
Lack of knowledge in the dosing principle including doser calibration (52.2%)	Mills should be trained on doser installation, calibration, and general equipment operation
Inconsistent premix supply (60%)	a. Advocate for local manufacture of premixes to ensure availability on demand b. The government should coordinate the premix supply.
The high cost of premix (45%)	Subsidize premix prices
Low-quality premix in the market (Stability) (34%)	a. KEBS should check the premixes to ensure only those that meet the set quality standards are allowed into the market b. The Government to provide capacity development of mills to allow them to check the quality of premix before purchase.
Lack of knowledge of licensed premix suppliers in the country (38%)	A database of all licensed premix suppliers in the country should be created and mills allowed accessing it so as they can make informed choices on whom to buy the premix from.
External monitoring is very expensive (40.2%)	KEBS should subsidize the cost of analysis
Lack of skills in fortification and standards (55%)	Mills should be trained in all aspects of fortification including premixes, dosers and dosing, internal monitoring and fortification standards
Delays in feedback from KEBS with regards to sample analysis and certification (63.4%)	a. KEBS should ensure prompt feedback to help mills act on any arising concerns immediately. b. If the low capacity for external monitoring, KEBS should outsource from other institutions like JKUAT to help in the analysis c. The government should establish regional laboratories to minimize the sample load for the national laboratories.
Consumer resistance to the purchase and use fortified maize flour due to public ignorance of fortification (11%)	Training to consumers to create awareness on fortification, the importance of consuming fortified products and how to identify fortified products in the market should be carried out
Inhomogeneity of premix in the flour due to inadequate mixing and poor quality premixes (15.2%)	Standard ways of dosing and mixing should be developed to ensure homogenous distribution of premix in the flour and subsequent compliance to set legal standards
Inadequate funds to implement fortification (49.6%)	Appropriate technologies that are customized, efficient, affordable, and sustainable for maize flour/meal fortification be developed and provided by suppliers to commercial maize mills.
Lack of political will to support fortification by mills	Continued lobbying/advocacy for maize flour/ meal fortification to be undertaken and persuaded vigorously at both the mill and political level to ensure scale-up of fortification in the country.
Low regulatory monitoring capacity	KEBS should have coordinated surveillance to improve

	regulatory monitoring
Fortification is an additional cost to the mill	Credit facilities should be availed to mills especially small and medium scale mills to enable them to acquire the necessary equipment needed to implement the maize flour fortification programs

4.3 Compliance Status of Fortified Maize Flour with Standards

4.3.1. Level of Compliance of Fortified Maize Flour with EAS 768

From the results, it is evident that the specific micronutrient analyzed (vitamin A, B_2, B_3, B_9 iron and zinc) in the flour samples were out of the range specified in the EAS768 for fortified flour. Even though according to the GOK directive about half of the samples analyzed met the requirement for compliance in at least three micronutrients analyzed (KEBS, 2012), only 11.1% of the samples complied in all the six micronutrients analyzed while 18.5% did not comply in a single micronutrient (**Figure 4.20**). Non-compliance, especially for vitamins, was mainly observed as the micronutrients did not meet the minimum legal limit specified in EAS768

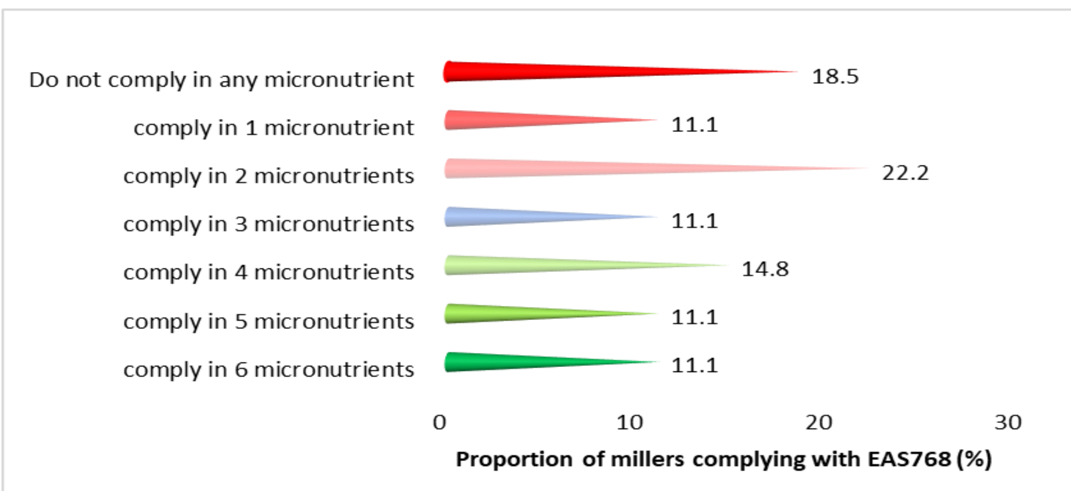


Figure 4.20: Micronutrient compliance status of fortified maize flour in Kenya

The most probable cause of low compliance was under-addition of fortification premix during milling, low quality of premixes, poor dosing rates, and degradation during storage (Luthringer et al., 2015). This ultimately affects the availability and intake of micronutrients by consumers of fortified flour. Therefore, it potentially prevents the desired reduction in vitamin and mineral deficiencies expected to be achieved through the flour fortification program (Dwyer et al., 2015). Higher amounts of micronutrients, above the maximum amount specified, were only observed in the minerals, zinc, and iron. Evidence of low compliance, for all the micronutrient analyzed, undermines the desired impact of flour fortification on the micronutrient health of Kenyans. This is mainly due to the inadequate access to the recommended amounts of vitamins and minerals expected to be obtained from the consumption of adequately fortified maize flour.

There was higher compliance for zinc and iron at 77.7% and 59.3% respectively compared to that of vitamins A, B_2, B_3, and B_9, at 33.3%, 29.6%, 33.3%, and 29.6% respectively (**Figure 4.21**). Over 40% of the flour samples that complied with zinc and iron did not meet the legal requirements for the vitamins. This is due to the higher stability of minerals compared to that of vitamins. Vitamins are generally prone to deterioration when exposed to environmental conditions like light, temperature, relative humidity, and oxygen (Dunn et al., 2014; Kuong et al., 2016).

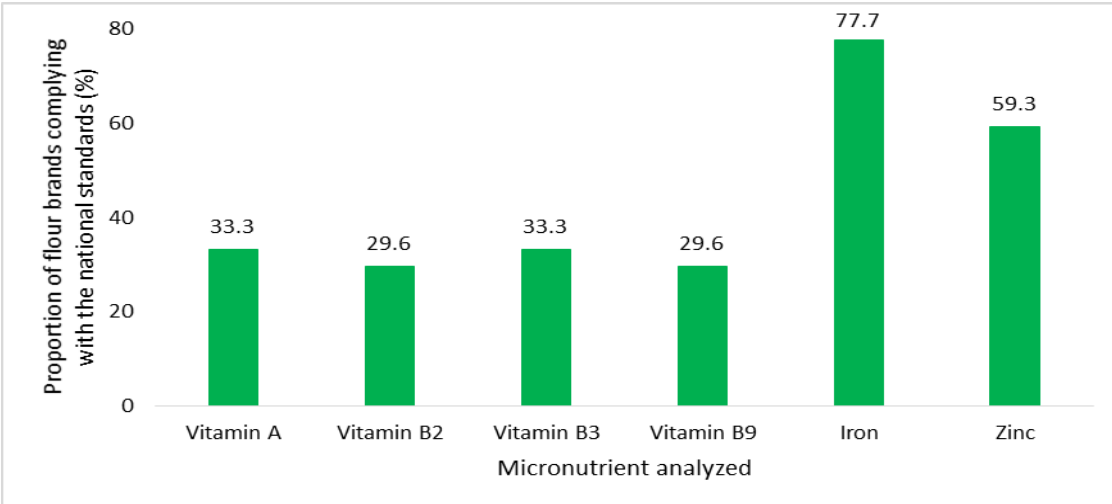


Figure 4.21: Micronutrient compliance status for fortified maize flour

Higher compliance for iron and zinc may be due to the higher stability of minerals compared to that of vitamins. From the survey (section 4.1.2.3), the commercial maize mills (69%) were storing the premixes at room temperature. This storage condition disposed the premix to light, oxygen and temperature which contribute to losses due to the instability of the vitamins (Dunn et al., 2014; Kuong et al., 2016). This may have contributed to the low compliance exhibited by the vitamins analyzed.

4.3.2. Compliance for specific micronutrients in fortified maize flour with national standards

4.3.2.1. Vitamin A (Retinyl palmitate)

The retinol contents for the flour samples analyzed ranged from levels below detectable limits to 1.2 mg/kg with a mean of 0.4±0.3 mg/kg. Only a third (33.3 %) of the samples complied with the standard of vitamin A in fortified maize flour (**Figure 4.22**).

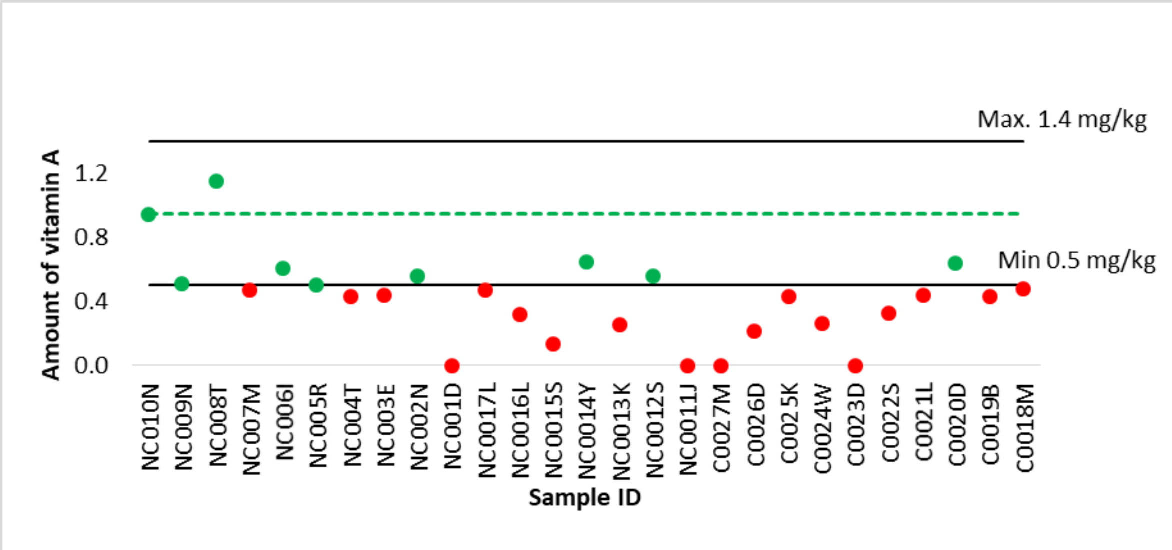


Figure 4.22: Compliance status for vitamin A (Retinol) in fortified maize flour

Samples from Nairobi/Central region had higher compliance (29.6%) compared to samples from the coast region (3.7%) This may be due to the difference in environmental conditions experienced in the two regions. Nairobi/Central region is cold and dry while the Coastal region is hot and humid (Wokabi, 2013). Temperature and relative humidity affect the stability of micronutrients in fortified foods (Dunn et al., 2014; Kuong et al., 2016). However, 14.8% of the samples had retinyl palmitate level below detectable limits

4.3.2.2. Vitamin B_2 (Riboflavin)

The amount of riboflavin in the flour samples analyzed ranged from 0.3 mg/kg to 4.0 mg/kg with an average of 1.5±1.0 mg/kg. **Figure 4.23** shows the amounts of riboflavin in the fortified maize flour samples analyzed. Only 29.6% of the samples had riboflavin content within 2 mg/kg to 5.8 mg/kg range. While no sample had riboflavin above 5.8

mg/kg, 59.3% of the samples had riboflavin content that was significantly below the minimum limit of 2 mg/kg. (Ekinci & Kadakal, 2005)

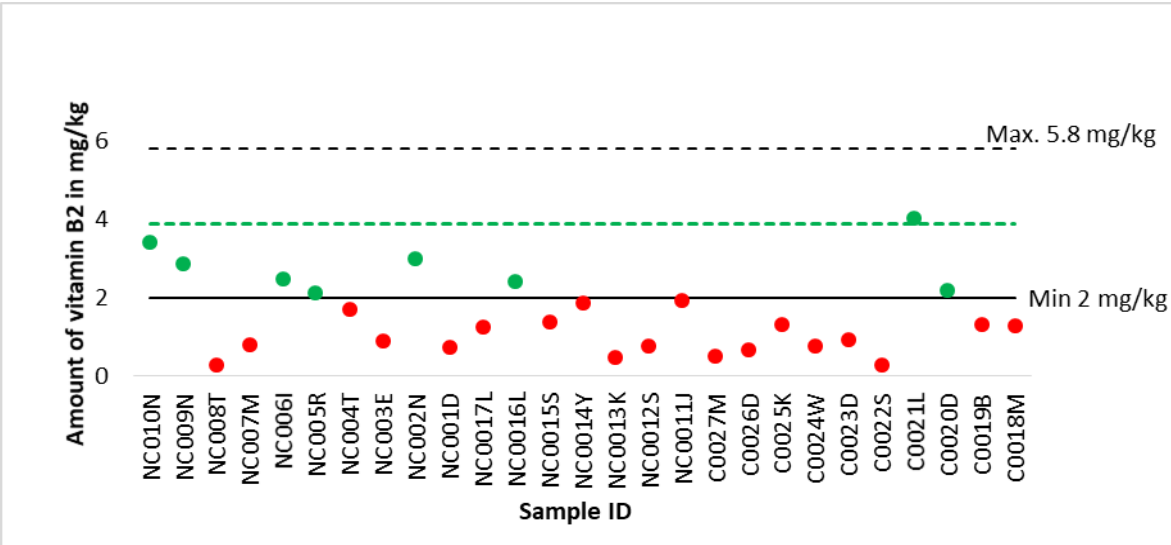


Figure 4.23: Vitamin B_2 compliance status for fortified maize flour

4.3.2.3. Vitamin B_3 (Niacin)

Niacin contents of fortified maize flour analyzed ranged from 6.6 mg/kg to 22.2 mg/kg with an average of 12±3.7 mg/kg. **Figure 4.24** shows the amounts of niacin in the fortified maize flour samples analyzed. Only one third (33.3%) of the samples analyzed had niacin within the set legal limits thus complied with the law.

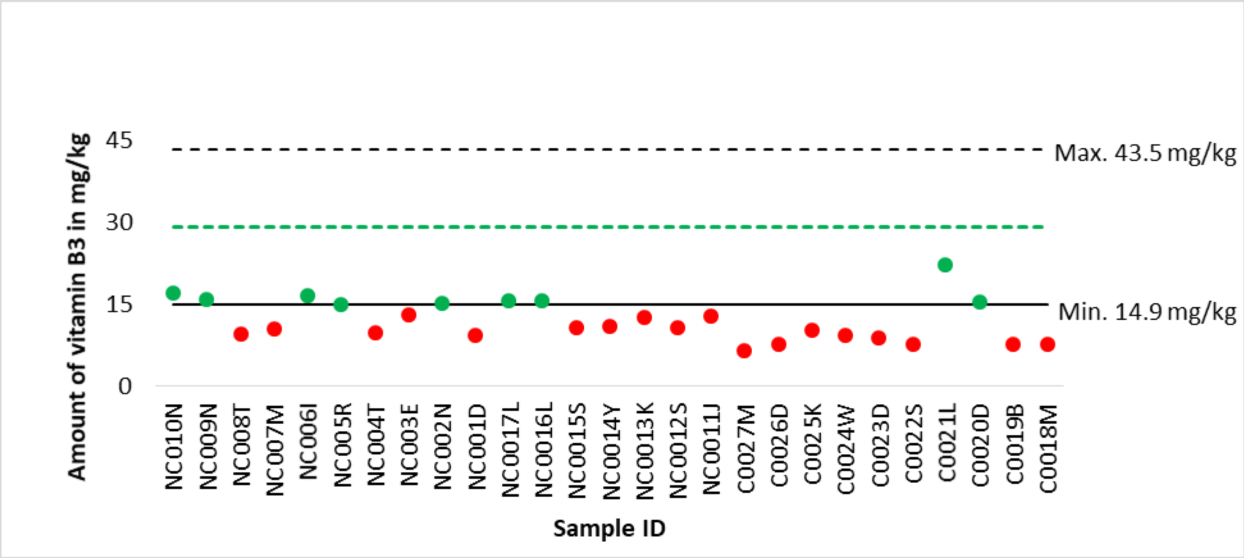


Figure 4.24: Vitamin B_3 compliance status for fortified maize flour

4.3.2.4. Folate (Vitamin B_9)

The flour samples analyzed had folic acid ranging those below detectable limits to 1.3 mg/kg with a mean of 0.4±0.3 mg/kg. **Figure 4.25** shows the amounts of folic acid in the fortified maize flour samples analyzed. About a third (29.6%) of the samples had folic acid amounts within the set legal limits of 0.6 mg/kg to 1.7 mg/kg while 11.1% had folic acid content below detectable limits.

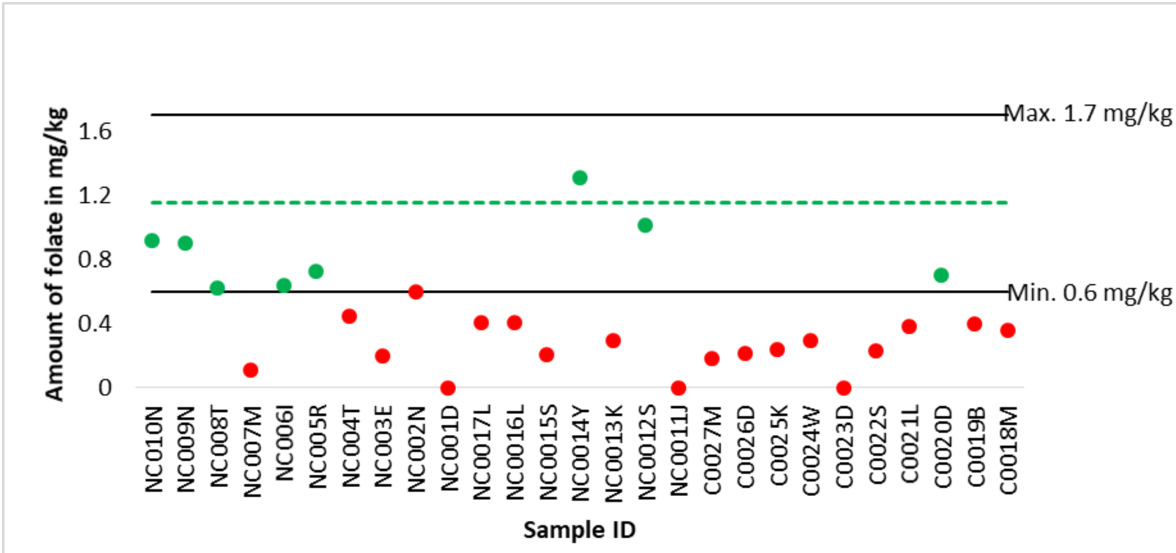


Figure 4.25: Folate compliance status for fortified maize flour

Vitamins are sensitive to heat, oxygen, light and acidic environments. In normal storage of maize flour, such conditions may prevail thus the possibility of low retention of the vitamin. Losses could be up to 50-90% for folate and 70-95% for retinol, 78% for riboflavin and 94% for niacin in storage (Dunn et al., 2014; Food Standards Australia New Zealand, 2006; Surma, 2010).

Adequate folate amount is desirable during pregnancy to prevent congenital malformations like neural tube defects, Vitamin B_2 and vitamin B_3 are important co-enzymes in energy metabolism while Infants and young children have increased vitamin A requirement to support rapid growth and help prevent the risk of infections. In pregnancy, vitamin A is essential for fetal growth and maturation, maintenance of maternal immunity, eye health and night vision (Castillo-Lancellotti, Tur, & Uauy, 2013; Das et al., 2013; Hamner & Tinker, 2014; WHO, 2009).

Approximately 11.1% and 14.8% of the samples analyzed had folate and retinol amounts below detectable limits, respectively. However, these micronutrients are of importance to the Kenyan population as their prevalence of deficiency in the population is high. The marginal vitamin A deficiency among pre-school children is 52.6% while folate deficiency among pregnant and non-pregnant women is 32.1% and 30.9% respectively (KNBS, 2011). With 66.7% and 70.4% of samples not complying with Vitamin A and folate standards respectively, there is less likelihood that fortification of maize flour will help reduce their prevalence significantly.

4.3.2.5. Iron

The iron contents for the flour samples analyzed ranged from 18.1 mg/kg to 54.5 mg/kg with a mean of 29.8±8.4 mg/kg. The compliance fortified maize flour with the standard for iron was 77.7%. However, 11.1% of the samples had iron levels that were not significantly lower than 21 mg/kg ($p<0.05$) (**Figure 4.26**).

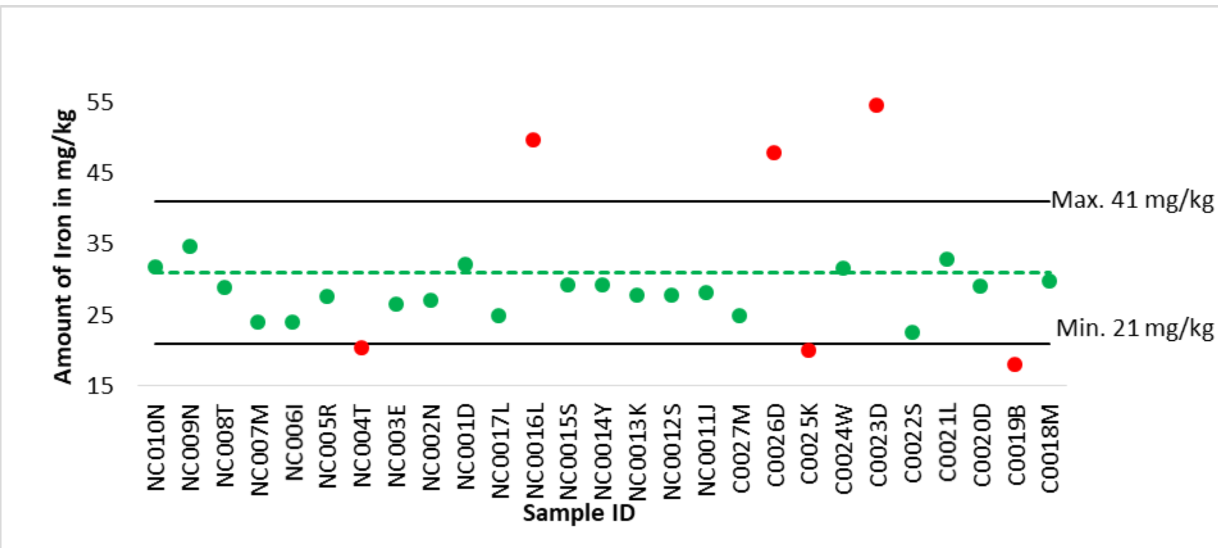


Figure 4.26: Iron compliance status for fortified maize flour

Iron fortification of flour is important to the Kenyan population as it is aimed at reducing the prevalence of iron deficiency among the vulnerable groups of the population. There is still a high prevalence of iron deficiency anaemia in the Kenyan population (26% in pregnant women, 12.5% in preschool children, 14% in school-aged children and 21.8%

in non-pregnant women (KDHS, 2014)) even with the high rate of compliance for iron fortification in maize flour. This may be as a result of intestinal malfunctions that affect the absorption of iron by the body other infections leading to diarrhea, vomiting and lack of appetite (World Health Organization, 2011). Overall, the prevalence of anaemia in Kenya was at 23.1% compared to 24.8% globally and 40.7% in Africa (KNBS, 2011). While there was high compliance (77.7%) for iron in fortified maize flour, 11.1% of the samples had iron amounts that were significantly higher than 41mg/kg. The high amount of iron in the system arising from the prolonged consumption of over-fortified flour may lead to hereditary disorders (Brewer, 2010; Goldhaber, 2003).

4.3.2.6. Zinc

The zinc contents for the flour samples analyzed ranged from 21 mg/kg to 76.8 mg/kg with a mean of 45±15.3 mg/kg. Compliance for zinc in fortified maize flour was 59.26% ($p<0.05$) (**Figure 4.27**).

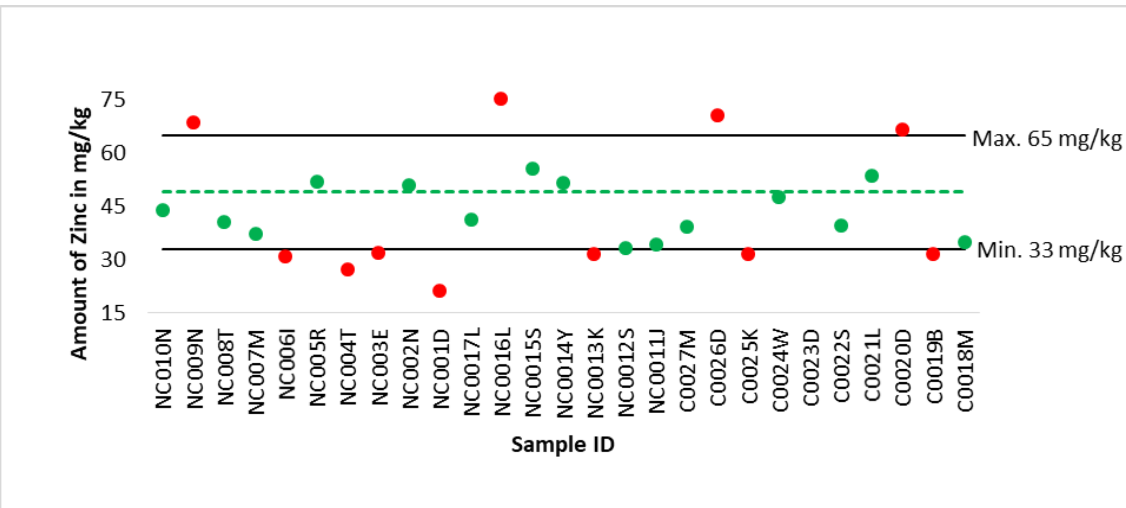


Figure 4.27: Zinc compliance status for fortified maize flour

Zinc fortification of flour is meant to reduce the effects of zinc deficiency on growth, neural development, and immunity. The prevalence of zinc deficiency in Kenya is

83.3% among all population groups, 82.3% for non-pregnant women, 80.2% among school-aged children, 74.8% in men and 68.3% in pregnant women (KNMS, 2017). The government of Kenya recommends the addition of zinc to maize flour within 33-65 mg/kg of flour (EAC, 2011). From the analysis, 7.4% of the samples had zinc amounts that were significantly below 33 mg/kg while 11.1% had zinc significantly above 65 mg/kg. Over-fortification of flour with zinc increases the risk of exposure to high doses of zinc which interferes with copper uptake leading to copper deficiency in the longterm (Plum, Rink, & Hajo, 2010).

About a tenth (11.1%) of the samples analyzed that complied with all the vitamins analyzed had zinc and iron amounts above the maximum legal limit of 65 mg/kg and 41 mg/kg respectively. This may have been as a result of overdosing to boost compliance of vitamins with standards due to their low retention capacity (Dunn et al., 2014; Peña-Rosas et al., 2014). Monitoring and evaluation of flour fortification should ensure adequate addition of micronutrients to the flour.

Consumption of fortified maize flour in Kenya may not achieve the desired health impact, especially among the vulnerable groups of the population, due to the high rates of non- compliance, especially for vitamins. The amount of premix added to the flour during fortification depends on the projected daily intake and the type of fortificant (Allen et al., 2006; Górniaczyk et al., 2017). This is important in estimating the number of micronutrients to be consumed by the population. This, however, is only possible if the flours are packaged well and stored in optimal conditions to allow high retention of the vitamin during storage.

4.4 Retention Capacity of Specific Vitamins in Fortified Maize Flour

Maize flour handling before consumption negatively influences the retention of vitamins added during fortification. Stability can, however, be ensured if the product is stored appropriately (Hemery et al., 2017). From the results, there was high retention in the vitamins for the samples stored at a lower range of temperature and relative humidity. According to Kuong, 2016 and Stoltzfus, 2008, temperature and relative humidity affects the stability of vitamins. Higher temperatures and relative humidity reduce the retention capacity of vitamins (Kuong et al., 2016; Stoltzfus et al., 2008).

4.6.1 Vitamin A (Retinyl Palmitate)

There was no significant difference in the amount of retinyl palmitate in the sample after one month of storage at 25ºC/RH 60% and 35ºC/RH 75% (**Table 4.13**).

Table 4.13: Retention of vitamins in fortified maize flour

	Riboflavin		**Niacin**		**Folate**		**Retinol**	
Storage conditions/ months	25°C/ 60%RH	35°C/75%RH	25°C/ 60%RH	35°C/75%RH	25°C/ 60%RH	35°C/75%RH	25°C/ 60%RH	35°C/75%RH
0	2.333^{a}± 0.034	2.333^{a}± 0.034	18.23^{a}± 0.088	18.231^{a}± 0.088	1.247^{a}± 0.013	1.247^{a}± 0.013	0.572^{a}± 0.004	0.572^{a}± 0.004
1	2.265^{a} ±0.042	2.235^{a}± 0.044	18.01^{a}± 0.006	17.27^{ab}± 0.58	1.242^{a}± 0.008	1.223^{ab} ±0.03	0.564^{ab} ±0.004	0.557^{a}± 0.005
2	2.175^{ab} ±0.04	2.11^{ab}± 0.06	17.782^{a} ±0.066	15.85^{ab}± 0.245	1.236^{a}± 0.004	1.195^{ab} ±0.09	0.55^{b}±0.001	0.524^{b}± 0.005
3	2.06^{ab}± 0.041	1.98^{ab}± 0.061	17.618^{a} ±0.209	15.559^{ab} ±0.181	1.227^{a}± 0.004	1.16^{ab}± 0.009	0.545^{b}± 0.001	0.499^{bc} ±0.004
4	1.91^{b}±0.04	1.883^{b}± 0.014	16.573^{a} ±0.3	15.282^{ab} ±0.139	1.19^{ab}± 0.026	1.148^{b}± 0.003	0.538^{b}± 0.005	0.474^{bc} ±0.004
5	1.68^{bc}± 0.078	1.4^{bc}±0.078	16.221^{a} ±0.245	14.407^{b} ±1.372	1.144^{b}± 0.006	1.006^{bc} ±0.037	0.514^{bc} ±0.001	0.453^{bc} ±0.002
6	1.54^{bc} ±0.08	1.269^{bc} ±0.086	15.99^{a}± 0.315	13.74^{b}± 0.75	1.09^{b}±0.01	0.95^{bc}± 0.018	0.479^{bc} ±0.001	0.433^{bc} ±0.003
P values	0.008	0.005	0.18	0.011	0.012	0.023	0.008	0.009

On average, there was a 16.2% reduction in the amount of retinol in fortified maize flour when stored at 25ºC/RH 60% for 6 months (**Figure 4.28**). This was lower than the 24.3% loss that occurred under 35ºC/RH 75% storage condition (**Figure 4.29**). This was different from the earlier findings of Dunn et al., 2014 that showed a 95% retention of retinol under 25ºC storage for 6 months, 72% retention under 45ºC storage for 3 months, and 75% retention at 27ºC for 6 months storage (Dunn et al., 2014). According to Kuong, 2016, retinol is more stable in cold and dry conditions than hot and humid environments (Kuong et al., 2016).

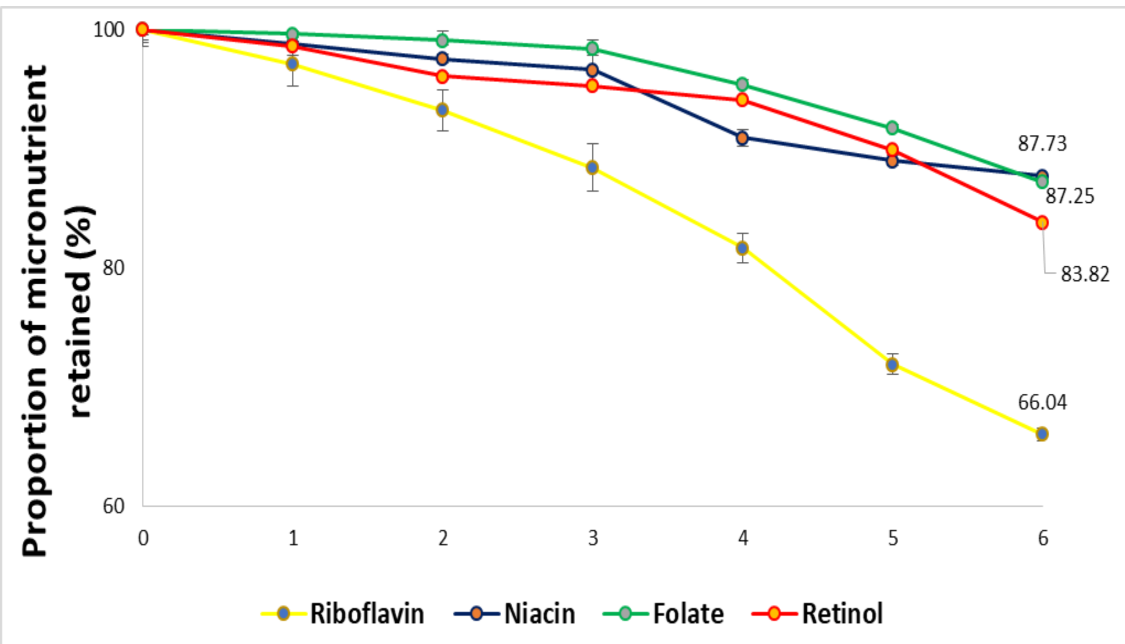


Figure 4.29: Retention of micronutrients in fresh fortified maize flour stored at 25°C/ 60%RH

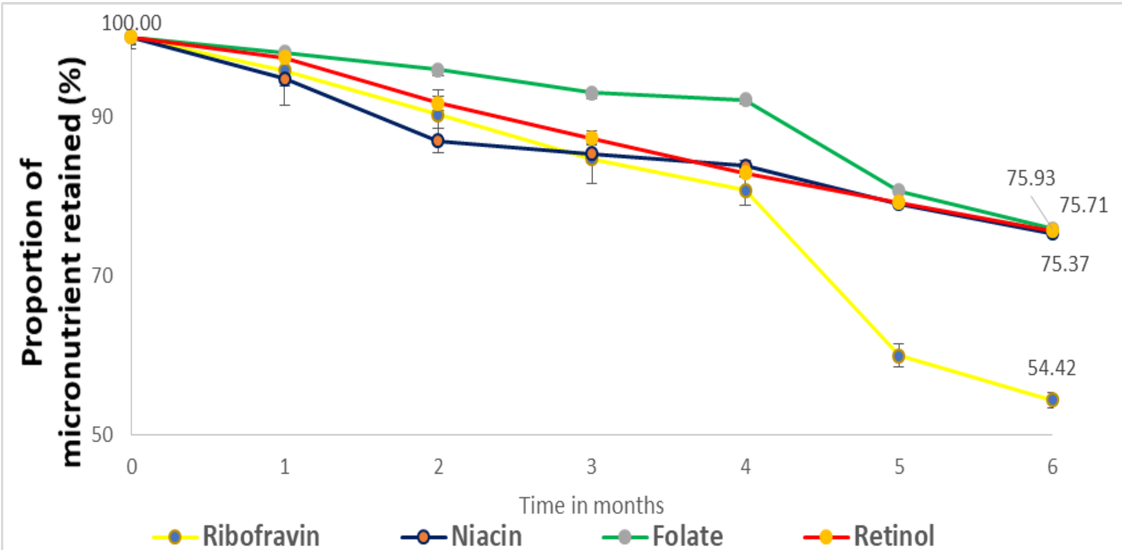


Figure 4.30: Retention of micronutrients in fresh fortified maize flour stored at 35°C/75%RH

4.6.2 Vitamin B2 (Riboflavin)

There was a reduction in the amount of riboflavin in fortified maize flour when stored at different conditions throughout the flour shelf-life. When flour was stored at 35ºC/RH 75% for 6 months, only 54.4% of riboflavin was retained (**Figure 4.30**) compared to 66.0% retention at 25ºC/RH 60% (**Figure 4.29**). This is different from the findings of USAID & DSM Nutritional Products, 1991, where when flour was stored in the dark for 3 months there was a 78% retention of riboflavin. According to USAID & DSM Nutritional Products, 1991, riboflavin is very stable even during thermal processing, storage, and food preparation. However, exposure to light makes it susceptible to degradation.

There was a significant loss of riboflavin in fortified flour (P=0.05) after 4 months of storage at 25ºC/RH 60%. The loss, however, was significant after 3 months of storage at 35ºC/RH 75%. The amount of riboflavin in flour stored at 25ºC/RH 60% was significantly different for that of the sample stored at 35ºC/RH 75% (**Table 4.13**).

4.6.3 Vitamin B3 (Nicotinamide)

Under the tested storage conditions after every month, retention of nicotinamide was higher at 25 ºC/RH 60% compared to 35ºC/RH 75%. After six months of storage, there was a nicotinamide retention capacity of 87.7% in fortified maize flour stored at 25ºC/RH 60% **(Figure 4.29)** and 75.6% retained at 35ºC/RH 75% (**Figure 4.30**).

Nicotinamide is the most stable vitamin with main losses occurring from leaching into the cooking water. From this study, there was no significant loss (p=0.05) in nicotinamide in flour samples stored at 25ºC/RH 60% (**Table 4.12**). This was observed as there was no significant difference in nicotinamide in the sample after 6 months of storage and in the fresh sample. However, there was a 24.4% loss in nicotinamide in the samples stored at 35ºC/RH 75% for six months. According to USAID and DSM, 1991, there was a 94 % retention of nicotinamide when flour was stored in the dark for 3 months (USAID & DSM Nutritional Products, 1991).

4.6.3 Folic acid

There was higher retention of folic acid in flour stored at 25ºC/RH 60% than the one stored at 35ºC/RH 75%. A 12.8% reduction in folic acid was observed at 25ºC/RH 60% storage after 6 months (**Figure 4.29**). This is half the amount of folic acid lost when flour was stored for the same period at 35ºC/RH 75% (**Figure 4.30**). There was a significant loss of folic acid after 5 months of storage at 25ºC/RH 60% (**Table 4.13**). This was similar to the folic acid lost after 3 months of storage at 35ºC/RH 75%. The highest proportion of folic acid was lost at the fifth (19.3%) and sixth (24.1%) month for the samples stored at 35 ºC/RH 75%.

Folic acid is unstable and loses activity in the presence of heat, light, oxidizing agents or reducing agents and acidic or alkaline environments (Surma, 2010). There was a 12.8% reduction in folic acid in the samples stored at 25ºC/RH 60 % compared to a 24.1% loss in samples stored at 35ºC/RH 75%. According to the Food Standards of Australia, folic acid losses of up to 50-90% under normal storage of maize flour may occur (Food Standards Australia New Zealand, 2006). This, however, contrasts the findings of Dunn, 2014, that indicate that folic acid is relatively stable to heat and humidity and can be retained 100% after 6 months of storage (Dunn et al., 2014; Production, 1991).

The latest micronutrient survey in Kenya revealed that the prevalence of Vitamin A deficiency among Pre-school children was 52.6% and Folate deficiency was at 32.1% in pregnant women and 30.9% in non-pregnant women (KNBS, 2011). This overemphasizes the need for the adequate fortification of flour with these micronutrients. However, with losses occurring during storage exhibited in the country, the government of Kenya needs to rethink the fortification strategy and work with premix supply to reconstitute the premixes and use more vitamins to cater to loses occurring in storage.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

The commercial maize mills surveyed operated at an average of 76% of their installed milling capacities. The market was dominated by large-scale mills that produced over three-quarters of the flour consumed despite their small number (28.2%). The majority of the labour force in the mills was unskilled. Roller milling was the predominant technology applied by the mills. All the large-scale mills implemented flour fortification. But the implementation rate among the medium and small-scale mills was low.

The implementation of commercial maize flour fortification, despite the law on mandatory fortification in the country, was still low with only 54% of the mills fortifying. This is attributed to the lack of reliable premix suppliers in the market, long premix importation periods, high cost and low-quality dosers, inadequate QA/QC capacity of the mills and inefficient regulatory monitoring of premix suppliers and commercial maize mills by KEBS and lack of knowledge in all aspects of milling and fortification.

The compliance level for fortified maize flour with the national standard (EAS768) was low. Only 22.2% of the samples complied with all the micronutrients considered in this study. Minerals had a higher compliance rate than vitamins in the analyzed samples. There was evidence of over-fortification for zinc and iron while some samples had folate and retinol levels below detectable limits.

Significant losses of vitamins were observed during storage. High temperature and relative humidity lead to an increased loss. Thus storage conditions for fortified maize flour (storage time, temperature and relative humidity) affect the retention capacity of vitamins.

5.2 Recommendations

There is a need to increase the coverage of flour fortification programs by commercial maize mills in Kenya. This can be achieved through concerted efforts, from the commercial maize milling industry, non-governmental organizations and the Government of Kenya through MOH and KEBS, to introduce and improve food fortification practice among medium and small scale maize mills and sustain the efforts of large-scale maize mills in food fortification.

Proposed reinforcing approaches to overcome the key challenges contributing to the slow adoption and implementation of flour fortification practices by the commercial mills include training of mills in food fortification practice, improve access to high quality premixes and dosers by mills, improve capacity of millers to conduct internal QA and improve surveillance of fortified maize flour and enforcement of food fortification regulatory standards.

Further studies should also be carried out to evaluate the optimum storage condition and packaging for fortified maize flour to improve micronutrient retention capacity. A comparison study for compliance of fortified maize flour at the point of production, retail and household level should be carried out to determine the critical points along the value chain contributing to non-compliance and ways to overcome such challenges

Monitoring and evaluation of the effectiveness of maize flour fortification in improving the micronutrient health of the Kenyan population should be carried out so as to improve the current and future management of outputs, outcomes and impact of the program.

REFERENCES

Abu, O., & Kirsten, J. F. (2009). Profit efficiency of small- and medium-scale maize milling enterprises in South Africa. *Development Southern Africa*, *26*(3), 354–368.

Aburto, N. J., Abudou, M., Candeias, V., & Wu, T. (2014). Effect of salt iodization to prevent iodine deficiency disorders: a systematic review with meta-analyses. *WHO ELibrary of Evidence for Nutrition Actions (ELENA)*, 142. Retrieved from:www.who.int/about/licensing/copyright_form/en/index.html%0Ahttp://apps.who.int/iris/bitstream/10665/148175/1/9789241508285_eng.pdf

Allen, L., Benoist, B. de, Dary, O., & Hurrell, R. (2006). Guidelines on Food Fortification With Micronutrients. *Who, Fao Un*, *341*, 4567- 4572.

AOAC. (2000). Official Methods of Analysis of AOAC International. *Association of Official Analysis Chemists International*, Method ce 2-66. https://doi.org/10.3109/15563657608988149

Atta, C. A. M., Fiest, K. M., Frolkis, A. D., Jette, N., Pringsheim, T., St Germaine-Smith, C., … & Metcalfe, A. (2016). Global birth prevalence of spina bifida by folic acid fortification status: A systematic review and meta-analysis. *American Journal of Public Health*, *106*(1), e24–e34.

Bailey, L. (2015). The Epidemiology of Global Micronutrient Deficiencies. *National Institutes of Health (NIH). Annals of Nutrition and Metabolism Published by S. Karger AG, 66*(suppl 2), 22–33.

Baro, M., & Deubel, T. F. (2006). Persistent Hunger: Perspectives on Vulnerability, Famine, and Food Security in Sub-Saharan Africa. *Annual Review of Anthropology, 35*(1), 521–538.

Beltrán-de-Miguel, B., Estévez-Santiago, R., & Olmedilla-Alonso, B. (2015). Assessment of dietary vitamin A intake (retinol, α-carotene, β-carotene, β-cryptoxanthin) and its sources in the National Survey of Dietary Intake in Spain (2009-2010). *International Journal of Food Sciences and Nutrition*, *66*(6), 706–712.

Bhutta, Z. A., Ahmed, T., Black, R. E., Cousens, S., Dewey, K., Giugliani, E., …& Kirkwood, B. (2008). Maternal and Child Undernutrition 3 What works ? Interventions for maternal and child undernutrition and survival. *Lancet, 371,* 417-40, 371.

Biban, B. G., & Lichiardopol, C. (2017). Iodine Deficiency, Still a Global Problem? *Current Health Sciences Journal*, *43*(2), 103–111.

Bothast, R. J., Warner, K., & Kwolek, W. F. (1981). Effects of Moisture and Temperature on Microbiological and Sensory Properties of Wheat Flour and Corn Meal During Storage. *Cereal Chem.*, *58*, 309–311.

Bouis, H., Low, J., McEwan, M., & Tanumihardjo, S. (2013). Biofortification: Evidence and lessons learned linking agriculture and nutrition. *FAO and WHO,* 1–23.

Bown, K., Hess, S., & Ave, H. (2010). Food and nutrition: Distracted? Tea might help you focus. *Science News*, *172*(13), 206–206.

Bratter, P., & Bratter, V. E. N. De. (2000). Global prevalence of micronutrient malnutrition and impact on the health of children. *Impacts of Agriculture on Human Health and Nutrition (Vol. I): Encyclopedia of Life Support Systems*, *I*.

Brewer, G. J. (2010). Risks of Copper and Iron Toxicity during Aging in Humans. *Toxicity,* 319–326.

Bryce, J., Coitinho, D., Darnton-Hill, I., Pelletier, D., & Pinstrup-Andersen, P. (2008). Maternal and child undernutrition: effective action at national level. *The Lancet*, *371*(9611), 510–526.

Butler, S. E., Muok, E. M., Montgomery, S. P., Odhiambo, K., Mwinzi, P. M. N., Secor, W. E., & Karanja, D. M. S. (2012). Mechanism of Anemia in Schistosoma mansoni – Infected School Children in Western Kenya. *American Journal of Tropical Medicine and Hygiene*, *87*(5), 862–867.

Castillo-Lancellotti, C., Tur, J. A., & Uauy, R. (2013). Impact of folic acid fortification of flour on neural tube defects: A systematic review. *Public Health Nutrition*, *16*(5), 901–911.

Caulfield, L. E., Richard, S. A., Rivera, J. A., Musgrove, P., & Black, R. E. (2006). Stunting, Wasting, and Micronutrient Deficiency Disorders. *Disease Control Priorities in Developing Countries*. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/21250337

Challenges, R. (2007). Investing in the Future : Ecological. In *Journal of Forestry*. *6*(5), 90–911.

Christianson, A., Howson, C., & Modell, B. (2006). Executiv E Summary. March of Dimes Executive Global Report on Birth Defects. *Journal of Tropical Medicine and Hygiene*, *8*(5), 862–867

Darnton-Hill, I., & Nalubola, R. (2002). Fortification strategies to meet micronutrient needs: successes and failures. *Proceedings of the Nutrition Society*, *61*, 231–241.

Dary, O., Freire, W., & Kim, S. (2003). Iron Compounds for Food Fortification: Guidelines for Latin America and the Caribbean 2002. *Nutrition Reviews*, *60*, S50–S61.

Das, J. K., Salam, R. A., Kumar, R., & Bhutta, Z. A. (2013). Micronutrient fortification of food and its impact on woman and child health: a systematic review. *Systematic Reviews*, *2*(1), 67

De-Regil, L. M., Finkelstein, J. L., Sæterdal, I., Gaitán, D., & Peña-Rosas, J. P. (2016). Fortification of wheat and maize flour with folic acid for population health outcomes. *Cochrane Database of Systematic Reviews*, *2016*(4), 3541- 3611.

Delgado, L. C. (2003). Animal source foods to improve micronutrient nutrition and human function in developing countries. *The Journal of Nutrition*, *133*(5), 3875S-4061S.

Dunn, M. L., Jain, V., & Klein, B. P. (2014). Stability of key micronutrients added to fortified maize flours and corn meal. *Annals of the New York Academy of Sciences*, *1312*(1), 15–25.

Dwyer, J. T., Wiemer, K. L., Dary, O., Keen, C. L., King, J. C., Miller, K. B., … Bailey, R. L. (2015). Fortification and Health : Challenges and Opportunities. *Adv. Nutrition*, *6*(1), 124–131.

Ekinci, R., & Kadakal, C. (2005). Determination of seven water-soluble vitamins in tarhana, a traditional Turkish cereal food, by high-performance liquid chromatography. *ACTA Chromatographica*, (15), 289–297.

Enzama, W., Afidra, R., Johnson, Q., & Verster, A. (2017). Africa Maize Fortification Strategy 2017-2026. *Smarter Futures*, 144. Retrieved from http://www.ffinetwork.org/regional_activity/images/Africa_Maize_Strategy_2017.pdf

Enzama, W., Roff wwwroffcoza, N., Randall, P., Verster, A., Vandenbroucke, M., & Johnson, Q. (2017). *Africa Maize Fortification Strategy prepared by The International Federation for Spina Bifida and Hydrocephalus Photograps: courtesy of Isak de*. Retrieved from http://ffinetwork.org/regional_activity/images/Africa_Maize_Strategy_2017.pdf

Fiedler, J. L., Afidra, R., Mugambi, G., Tehinse, J., Kabaghe, G., Zulu, R., … Bermudez, O. (2014). Maize flour fortification in Africa: Markets, feasibility, coverage, and costs. *Annals of the New York Academy of Sciences*, *1312*(1), 26–39.

Flanders, W. D., Bell, C., Mwihia, J., Ogana, G., Likimani, S., & Straetemans, M. (2011). *Comprehensive Assessment of Maize Aflatoxin Levels in Eastern Kenya, 2005–2007*. (12), 2005–2007.

Flour Fortification Initiative (FFI). (2008). *Second Technical Workshop on Wheat Flour Fortification: Practical Recommendations for National Application*. 1–24.

Flour fortification initiative, 2008. (2008). *Recommended Practices for the Production and Procurement of Premix Used in Cereal Fortification*. (April), 1–15.

Food, N., Policy, N. S., Survey, H., & Standards, W. H. O. G. (2011). *Kenya : Situation analysis for Transform Nutrition*. (2008), 1–13.

Food Standards Australia New Zealand. (2006). *Final Assessment Report: Proposal P295. Consideration of mandatory fortification with folic acid*. (July).

GAIN. (2012). Lessons Learned From 10 Years of Experience in Africa *: Sharing Experiences in Food Fortification*. *1*, 18–19.

GAIN. (2017). Challenges in the Regulatory Monitoring of Fortified Foods.

Fortification. *3*, 118–219.

Garcia-Casal, M. N., Peña-Rosas, J. P., De-Regil, L. M., Gwirtz, J. A., & Pasricha, S. R. (2018). Fortification of maize flour with iron for controlling anaemia and iron deficiency in populations. *Cochrane Database of Systematic Reviews*, *2018*(12), 765- 772.

GlobalReport. (2009). *Investing in the future Global report 2009*.

Gok, & KNBS. (2017). *Economic Survey 2017*. Retrieved from http://www.devolutionplanning.go.ke/images/hb/Economic Survey 2017.pdf

Goldhaber, S. B. (2003). Trace element risk assessment : essentiality,. *toxicity*. *38*, 232–242.

Górniaczyk, A., Czech-Szczapa, B., Sobkowski, M., & Chmaj-Wierzchowska, K. (2017). Maternal health-related behaviours during pregnancy: a critical public health issue. In *European Journal of Contraception and Reproductive Health Care*, *22*, 133-138

Grant, J. P. (2016). The state of the world’s children 1993. In Geneva: United Nations Children’s Fund.

Gupta, P. K., & Varshney, R. K. (2013). Cereal genomics II. *Cereal Genomics II*, *9789400764*, 1–438.

Gwirtz, J. A., & Garcia-Casal, M. N. (2014). Processing maize flour and corn meal food products. *Annals of the New York Academy of Sciences*, *1312*(1), 66–75.

Hamner, H. C., & Tinker, S. C. (2014). Fortification of corn masa flour with folic acid in the United States: An overview of the evidence. *Annals of the New York Academy of Sciences*, *1312*(1), 8–14.

Hannon, E. M., Kiely, M., & Flynn, A. (2007). The impact of voluntary fortification of foods on micronutrient intakes in Irish adults. *British Journal of Nutrition*, *97*(6), 1177–1186.

Harika, R., Faber, M., Delgado, L. C., Future, T., Relations, G., Kuong, K., …& DSM. (1982). Chapter II. *North-Holland Mathematical Library*, *25*(C), 79–96.

Hemery, Y. M., Laillou, A., Fontan, L., Jallier, V., Berger, J., & Avallone, S. (2017). Storage conditions and packaging greatly affects the stability of fortified wheat flour : influence on vitamin A , iron , zinc , and oxidation French National Research Institute for Sustainable Development (IRD), UMR Nutripass. *Food Chemistry*. *97*(6), 1177–1186.

Hoddinott, J., & Yohannes, Y. (2002). *Dietary Diversity as a Food Security Indicator. FCND Discussion Paper No 136.* (136).

Hodge, J., & Amuna, P. (2014). *Food fortification : A techno-fix or a sustainable solution to fight hidden hunger ?*

Israel, G. D. (1992). Determining Sample Size. *University of Florida Cooperative Extension Services, Instititute of Food and Agriculture Sciences*, *85*(3), 108–113.

Johnson, Q., Mannar, V., & Ranum, P. (2004). *Fortification Handbook Vitamin and Mineral Fortification of Wheat Flour and Maize Meal*. (June), 1–107.

Kai, O. K., & Roberts, D. J. (2008). The pathophysiology of malarial anaemia: Where have all the red cells gone? *BMC Medicine*, *6*, 4–7.

KEBS. (2012). *Monitoring and sampling of fortified foods - guidelines*. Nairobi: KEBS.

Keith, P. & West, Jr., D. (2006). Iodine Iodine Deficiency Iodine Deficiency Disorders (

IDD) Most preventable cause of mental retardation in the world. *Center for Human Nutrition*.

Kenya National Bureau of Statistics (KNBS); ORC Macro. (2010). Kenya Demographic and Health Survey 2008-09. *Health (San Francisco)*, 1–314.

KNBS. (2011). *The Kenya National Micronutrient Survey*. Retrieved from http://www.nutritionhealth.or.ke/wp-content/uploads/Downloads/The Kenya National Micronutrient Survey 2011.pdf

Kodentsova, V. M., Vrzhesinskaya, O. A., & Bessonov, V. V. (2011). Quality requirements for vitamins in the premix and nutritional supplements. *Voprosy Pitaniia*, *80*(6), 43–46.

Kuong, K., Laillou, A., Chea, C., Chamnan, C., Berger, J., & Wieringa, F. T. (2016). Stability of vitamin a, iron and zinc in fortified rice during storage and its impact on future national standards and programs—Case study in Cambodia. *Nutrients*, *8*(1), 3–11.

Luthringer, C. L., Rowe, L. A., Vossenaar, M., & Garrett, G. S. (2015). Regulatory Monitoring of Fortified Foods: Identifying Barriers and Good Practices. *Global Health: Science and Practice*, *3*(3), 446–461.

Makhumula, P., Dary, O., Guamuch, M., Tom, C., Afidra, R., & Rambeloson, Z. (2014). Legislative frameworks for corn flour and maize meal fortification. *Annals of the New York Academy of Sciences*, *1312*(1), 91–104.

Masoud, A. R. (2013). *the Role of Kenyan Maize Millers in Ensuring Food Security in East Africa*.

Mburu, A. S. W., Thurnham, D. I., Mwaniki, D. L., Muniu, E. M., & Alumasa, F. M.

(2010). The influence of inflammation on plasma zinc concentration in apparently healthy , HIV þ Kenyan adults and zinc responses after a multi-micronutrient supplement. *European Journal of Clinical Nutrition*, *64*(5), 510–517.

Meng, L., Wang, Y., Li, T., Loo-Bouwman, C., Zhang, Y., & Man-Yau Szeto, I. (2018). Dietary Diversity and Food Variety in Chinese Children Aged 3–17 Years: Are They Negatively Associated with Dietary Micronutrient Inadequacy? *Nutrients*, *10*(11), 1674.

Moretti, D., Biebinger, R., Bruins, M. J., Hoeft, B., & Kraemer, K. (2014). Bioavailability of iron, zinc, folic acid, and vitamin A from fortified maize. *Annals of the New York Academy of Sciences*, *1312*(1), 54–65.

Muyanga et al. (2006). Staple food consumption patterns in urban Kenya: Trends and policy implications. *Tegemeo Institute of Agriculture Policy and Development*, *Egerton University*, *Working pa* (02), 11–12.

Muyanga, M., Jayne, T. S., Argwings-Godhek, & Joshua, A. (2006). *Staple food consumption patterns in urban Kenya: Trends and Policy Implications Tegemeo Institute of Agricultural Policy and Development*. (02).

Mwaniki, A. (2007). Biofortification as a Vitamin A Deficiency Intervention in Kenya. *Ecology of Food and Nutrition*, *3–7*, 1–11.

Ngeno., V., C., M., K., L. B., M., N. P., K., S. A., & J., K. M. (2011). Technical efficiency of maize farmers in Uasin Gishu district , Kenya. *African Crop Science Conference Proceedings*, *10*, 41–47. Retrieved from http://www.acss.ws/Upload/XML/Research/746.pdf

Nyariki, D. M., Wiggins, S. L., & Imungi, J. K. (2002). Levels and causes of household food and nutrition insecurity in dryland Kenya. *Ecology of Food and Nutrition*, *41*(2), 155–176.

Oikeh, S. O., Menkir, A., Maziya-Dixon, B., Welch, R., & Glahn, R. P. (2003). Assessment of concentrations of iron and zinc and bioavailable iron in grains of early-maturing tropical maize varieties. *Journal of Agricultural and Food Chemistry*, *51*(12), 3688–3694.

Oino, P. G., Sorre, B., & Kareithi, J. (2017). *Household Maize Consumption Behavior and Food Loss in*. *3*(8), 13–25.

Otieno, D., & Okello, J. (2011). *Consumer awareness of food fortification in kenya : the case of vitamin-a-fortified sugaR Authors : Kennedy Pambo , David Otieno and Julius Okello Department of Agricultural Economics,* Nairobi: University of Nairobi.

Pambo, K. O., Otieno, D. J., & Okello, J. J. (2017). Original Article Analysis of Consumer Preference for Vitamin A-Fortified Sugar in Kenya. *The European Journal of Development Research*, *29*(4), 745–768.

Peña-Rosas, J. P., Garcia-Casal, M. N., Pachón, H., Mclean, M. S., & Arabi, M. (2014). Technical considerations for maize flour and corn meal fortification in public health: Consultation rationale and summary. *Annals of the New York Academy of Sciences*, *1312*(1), 1–7.

Pena-Rosas, J. P., Parvanta, I., Van Der Haar, F., & Chapel, T. J. (2008). Monitoring and evaluation in flour fortification programs: Design and implementation considerations. *Nutrition Reviews*, *66*(3), 148–162.

Plum, L. M., Rink, L., & Hajo, H. (2010). The essential toxin: Impact of zinc on human health. *International Journal of Environmental Research and Public Health*.

29(4), 745–768.

Production, W. S. (1991). Fortification Criteria. *Nutrition*, (Table 1), 1–4. Retrieved from http://www.dsm.com/products/nip/en_US/publications-page/publications-fortificationbasics.html

Ranum, P., & Pe, J. P. (2014). *Global maize production , utilization , and consumption*. *1312*, 105–112.

Rashid, I., & Potts, D. (1980). A Research Note Riboflavin Determination In Milk Inayat, *Rashid and Donald Potts (1978). 45*, 744–745.

Ruel, M. T. (2003). Operationalizing Dietary Diversity: A Review of Measurement Issues and Research Priorities. *The Journal of Nutrition*, *133*(11), 3911S-3926S.

Sablah, M., Grant, F., & Fiedler, J. L. (2013). Food Fortification in Africa Progress to date and priorities moving forward. *Sight and Life*, *27*(3), 18–24. Retrieved from:http://www.sightandlife.org/fileadmin/data/Magazine/2013/27_3_2013 /food_fortification_in_africa.pdf

Saeterdal, I., Mora, J. O., & De-Regil, L. M. (2012). Fortification of staple foods with vitamin A for preventing vitamin A deficiency. *Cochrane Database of Systematic Reviews*, (9). https://doi.org/10.1002/14651858.CD010068

Seleka, T. B., Jackson, J. C., Batsetswe, L., & Kebakile, P. G. (2011). Small-scale milling and the feasibility of mandatory fortification of sorghum and maize flour in Botswana. *Development Southern Africa*, *28*(4), 461–476.

Seshadri, S. (2001). Prevalence of micronutrient deficiency particularly of iron, zinc and folic acid in pregnant women in South East Asia. *British Journal of*

Nutrition, *85*(S2), S87.

Shah, D., Sachdev, H. S., Gera, T., De-Regil, L. M., & Peña-Rosas, J. P. (2016). Fortification of staple foods with zinc for improving zinc status and other health outcomes in the general population. *Cochrane Database of Systematic Reviews*, *2016*(6), 345- 354.

Smith, J. L., & Brooker, S. (2010). *Impact of hookworm infection and deworming on anaemia in non-pregnant populations : a systematic review*. *15*(7), 776–795.

Steyn, N., Nel, J., Nantel, G., Kennedy, G., & Labadarios, D. (2006). Food variety and dietary diversity scores in children: are they good indicators of dietary adequacy? *Public Health Nutrition*, *9*(5), 644–650.

Stoltzfus, R. J., & Dreyfuss, M. L. (1998). *Guidelines for the use of iron supplements to prevent and treat iron deficiency anemia. The International Nutritional Anemia Consultative Group (INACG/WHO/UNICEF), Washington, DC.* Retrieved from http://www.who.int/nutrition/publications/micronutrients/guidelines_for_Iron_supplementation.pdf

Stoltzfus, R. J., Smith, J. L., Brooker, S., Dror, D. K., Allen, L. H., Mburu, A. S. W., … Flour fortification initiative, 2008. (2008). Vitamin Stability in Premixes and Feeds A Practical Approach in Ruminant Diets. *Nutrients*, *9*(5), 3875S-4061S.

Sullivan, K., Nichols, E., Aburto, N., Masa, H., Wirth, J., Sullivan, K., & Serdula, M. (2012). *Performance of Iron Spot Test with Arabic Bread Made from Fortified White Wheat Flour Performance of iron spot test with Arabic bread made from fortified white wheat flour*. *Journal of Food and Nutrition Sciences*, *60*(2), 147–151.

Sürie, C., & Wagner, M. (2008). Supply chain analysis. *Supply Chain Management and Advanced Planning (Fourth Edition): Concepts, Models, Software, and Case Studies*, (September), 37–63.

Surma, M. (2010). Effect of storage conditions on folic acid content in folic acid-fortified bread - A model study. *Polish Journal of Food and Nutrition Sciences*, *60*(2), 147–151.

Uauy, R., Hertrampf, E., & Reddy, M. (2002). Forging Effective Strategies to Combat Iron Deficiency Iron Fortification of Foods : *Overcoming Technical and Practical Barriers 1 , 2 , 3*. 849–852.

USAID, (2010). Stape Foods Value Chain Analysis. *Report*, Nairobi: USAID.

van den Wijngaart, A., Bégin, F., Codling, K., Randall, P., & Johnson, Q. W. (2013). Regulatory monitoring systems of fortified salt and wheat flour in selected ASEAN countries. *Food and Nutrition Bulletin*, *34*(2 Suppl), 102–111.

Wagah, M. a., Bader, E., Deligia, C., & Dop, M. C. (2005). Nutrition Country Rrofile: Republic of Kenya. *Kenya Nutrition Profile – Food and Nutrition Division*, 31–32.

Weinberg, Z. G., Yan, Y., Chen, Y., Finkelman, S., Ashbell, G., & Navarro, S. (2008). *The effect of moisture level on high-moisture maize (Zea mays L .) under hermetic storage conditions — in vitro studies*. *44*, 136–144.

WHO. (2007). *Assessment of the iodine deficiency disorders and monitoring their elimination.*, Geneva: WHO.

WHO. (2009). G*lobal prevalence of vitamin A deficiency in populations at risk 1995-2005 : WHO global database on vitamin A deficiency*. Geneva: WHO.

WHO. (2014). What is hidden hunger? *Nutrition Topocs*. Geneva: WHO.

WHO and FAO. (2007). CODEX Alimentarious Cereals, pulses, legumes and vegetable proteins. In *Codex Standard For Certain Pulses Codex Stan 171-1989 (Rev. 1-1995)*.

Wokabi, S. M. (2013). Sustainability of Maize production in Kenya. *Kenya Agricultural Research Institute, Nairobi, Kenya*, *5*(2), 2. Retrieved from http://www.ces.iisc.ernet.in/energy/HC270799/LM/SUSLUP/Thema2/311/311.pdf

World Health Organization. (2011). the Global Prevalence of Anaemia in 2011. *WHO Report*, 48. Geneva: WHO.

Zahar, M., & Smith, D. E. (1990). Vitamin A quantification in fluid dairy products: rapid method for vitamin A extraction for high performance liquid chromatography. *Journal of Dairy Science, 73(12), 3402-3407.*

Zamora, G., & De-Regil, L. M. (2014). Equity in access to fortified maize flour and corn meal. *Annals of the New York Academy of Sciences*, *1312*(1), 40–53.

Zimmermann, M. B., & Andersson, M. (2012). Update on iodine status worldwide. *Current Opinion in Endocrinology, Diabetes and Obesity*, *19,* 382–387.

APPENDICES

Appendix I: Commercial Maize Mills Surveyed

REGION	COMMERCIAL MAIZE MILL	COUNTY	TOWN	YEAR ESTABLISHED
Nairobi/Central	Unga limited	Nairobi	Nairobi	1908
Nairobi/Central	MMM-Runyenjes	Nairobi	Nairobi	1997
Nairobi/Central	Range processors ltd	Nairobi	Nairobi	2014
Nairobi/Central	Faulu flour mills	Nairobi	Nairobi	2017
Nairobi/Central	Mombasa maize millers	Nairobi	Nairobi	2000
Nairobi/Central	Summer millers ltd	Kiambu	Ruiru	2008
Nairobi/Central	Family flour	Kiambu	Ruiru	2010
Nairobi/Central	Umoja maize millers ltd	Kiambu	Thika	
Nairobi/Central	Transmillers ltd	Kiambu	Thika	2012
Nairobi/Central	Bellamy milling company	Kirinyaga	Sagana	1976
Nairobi/Central	Centaur milling company	Kirinyaga	Sagana	2001
Nairobi/Central	Dandora maize millers	Nairobi	Nairobi	1989
Nairobi/Central	Alpha grain millers	Nairobi	Nairobi	2011
Nairobi/Central	MMM-NRB ltd	Nairobi	Nairobi	
Nairobi/Central	Worldpeak International ltd	Nairobi	Nairobi	2017
Nairobi/Central	Salama millers	Nyeri	Karatina	2008
Nairobi/Central	Balesa millers	Kirinyaga	Kiandai	2017
Nairobi/Central	Daiga millers	Laikipia	Nanyuki	2000
Eastern/North-Eastern	Mkulima Flour mills	Machakos	Athi River	2015
Eastern/North-Eastern	Fina Supplies ltd	Machakos	Mulolongo	2015
Eastern/North-Eastern	Mwanzo mpya trading co. ltd	Machakos	Masii	2010

Eastern/North-Eastern	Eastern flour millers	Machakos	Machakos	1992
Nairobi/Central	Joymax millers	Kirinyaga	Kutus	2014
Nairobi/Central	Victor maize millers	Kirinyaga	Kagio	2016
Eastern/North-Eastern	Lizhbrand multcare	Embu	Kairuri	2015
Eastern/North-Eastern	Khifam limited	Embu	Runyenjes	2014
Eastern/North-Eastern	County millers	Embu	Ugweri	2012
Eastern/North-Eastern	Kapari millers	Embu	Kianjokoma	2008
Eastern/North-Eastern	Embu food industries	Embu	Embu	2008
Eastern/North-Eastern	Jambo millers	Murang'a	Maragwa	2007
Nairobi/Central	Farina maize millers	Murang'a	Kiriani	2016
Nairobi/Central	Cornstar maize millers	Murang'a	Kenol	2017
Nairobi/Central	Nanyuki grain millers	Laikipia	Nanyuki	2017
Nairobi/Central	Likii maize millers	Laikipia	Nanyuki	
Eastern/North-Eastern	Grits industries	Kitui	Kitui	2010
Eastern/North-Eastern	Joli millers	Machakos	Matuu	1998
Eastern/North-Eastern	Matuu flour millers	Machakos	Matuu	2014
Eastern/North-Eastern	Century millers	Machakos	Matuu	2016
Eastern/North-Eastern	Eldoret grains	Kitui	Mwingi	1988
Nairobi/Central	Cateress Milling Company	Nairobi	Nairobi	1993
Nairobi/Central	Witman enterprises	Nairobi	Nairobi	2016
Nairobi/Central	Vikat Millers	Nairobi	Nairobi	2015
Nairobi/Central	Magutu grain millers ltd	Nairobi	Mulolongo	2017
South Rift	Wasam Millers	Nakuru	Nakuru	1995
South Rift	Unga zaidi millers	Nakuru	Nakuru	2014
South Rift	Ufa unga millers	Nakuru	Nakuru	2006
South Rift	Theducat ent. ltd	Nakuru	Nakuru	2014
South Rift	Economy millers	Nakuru	Njoro	2015
South Rift	Naku modern feeds ltd	Nakuru	Nakuru	1997

South Rift	Amani flour mills	Nakuru	Njoro	2007
South Rift	Lanet flour mills	Nakuru	Lanet	2012
South Rift	Food chain ltd	Nakuru	Nakuru	2011
South Rift	Beade millerltd	Nakuru	Maili kumi	2014
South Rift	Mois BridgeGrains ltd	Nakuru	Gilgil	2016
South Rift	Gilgil grains ltd	Nakuru	Gilgil	1907
South Rift	Magjom flour mill	Nakuru	Lanet	2001
Coast	Lola loal industry ltd	Kilifi	Malindi	2015
Coast	Malindi flour mills	Kilifi	Malindi	2017
Coast	Karibu	Mombasa	Mombasa	2015
Coast	Kitui flour mills	Mombasa	Mombasa	1989
Coast	Biladi	Kilifi	Mtwapa	2011
Coast	Mombasa maize millers	Mombasa	Mombasa	1980
Western/Nyanza	Demand millers	Homabay	Oyugis	2017
Western/Nyanza	Mombasa maize millers	Kisumu	Kisumu	
Western/Nyanza	Western deluxe maize co ltd	Busia	Busia	
North Rift	Kitale industries ltd	Trans nzoia	Kitale	1987
North Rift	Unga ltd Eldoret	Uasin Gishu	Eldoret	1985
North Rift	Bapa millers	Trans nzoia	Mois Bridge	2014
North Rift	Cornbelt flour mills	Uasin Gishu	Moi Bridge	2015
North Rift	Jamii milling ltd	Uasin Gishu	Moiben	2015
North Rift	Nzoia grain millers	Trans Nzoia	Endebess	2017
North Rift	Maize milling co. ltd	Uasin Gishu	Eldoret	2001

Appendix II: Flour Brands Sampled for Compliance Analysis

	County	Town	Company name	Brand	Date of sampling	Place of sampling	Date of manufacture	Date of expiry
1	Nairobi	Nairobi	Dandora maize millers	Harmony	29/05/2018	DanMill Wholesellers-Dandora	7/5/2018	7/8/2018
2	Nairobi	Nairobi	MMM-Runyenjes	Ndovu	29/05/2018	Maathai supermarket-Nairobi	13/05/2018	30/09/2018
3	Nairobi	Nairobi	Worldpeak international ltd	PAA	29/05/2018	Maathai supermarket-Nairobi		31/08/2018
4	Kiambu	Thika	Maycorn	Maycorn	29/05/2018	Maathai supermarket-Nairobi	23/04/2018	22/08/2018
5	Nairobi	Nairobi	MMM-Runyenjes	Cosmo	29/05/2018	Maathai supermarket-Nairobi	Mar-18	8/24/2018
6	Nairobi	Nairobi	Unga limited	Hostess	29/05/2018	Maathai supermarket-Nairobi	5/5/2018	5/9/2018
7	kiambu	Thika	Mama millers	Mama	29/05/2018	Maathai supermarket-Nairobi	May-18	8/31/2018
8	Nairobi	Nairobi	Nairobi Flour mills	Jimbi	29/05/2018	Maathai supermarket-Nairobi	May-18	10/30/2018
9	Nairobi	Nairobi	Alpha grain millers	Kifaru	29/05/2018	Maathai supermarket-Nairobi	24/05/2018	23/10/2018
10	Nairobi	Nairobi	Unga limited	Jogoo	29/05/2018	Maathai supermarket-Nairobi	6/5/2018	6/9/2018
11	Kiambu	Thika	Umoja maize millers ltd	Lucky star	21/06/2018	Leestar supermarket-makongeni	Jun-18	31/12/2018
12	Kirinyaga	Sagana	Bellany milling company	Tajiri	21/06/2018	Bellamy wholesalers-sagana	Jun-18	10/30/2018
13	Kirinyaga	Sagana	Centaur milling company	Karibu nyumbani	21/06/2018	Times telcom shop-Sagana	May-18	30/11/2018
14	Nyeri	Karatina	Salama millers	Salama	21/06/2018	salama wholesalers-Karatina		31/12/2018

15	Laikipia	Nanyuki	Daiga millers	Farasi HodariHodari	21/06/2018	Daiga millers town outlet-Nanyuki		31/12/2018
16	Laikipia	Nanyuki	Daiga millers	Daiga maize meal	21/06/2018	Daiga millers town outlet-Nanyuki		28/02/2019
17	Laikipia	Nanyuki	Simba Mfalme Millers	Simba	21/06/2018	Moyale wholesalers-Nanyuki		31/01/2019
18	Mombasa	Mombasa	Kitui flour mills	Dola	8/8/2018	Budget supermarket-Posta, Mombasa	7/4/2018	12/4/2018
19	Mombasa	Mombasa	MMM-Mombasa	Taifa	8/9/2018	Msafiri Butchery-Malindi	7/29/2018	1/29/2019
20	Mombasa	Mombasa	Kitui flour mills	Maisha	8/8/2018	Naivas spmt-Bamburi	6/24/2018	11/24/2018
21	Mombasa	Mombasa	MMM-Mombasa	Bahari	8/9/2018	Sales Office MMM-Mombasa	8/9/2018	2/9/2019
22	Mombasa	Mombasa	MMM-Mombasa	Tima	8/9/2018	MMM-factory outlet, Sabasaba	8/9/2018	2/9/2019
23	Kilifi	Malindi	Malindi flour mills	Riziki	8/7/2018	Abuhawat investment-malindi	7/3/2018	1/3/2019
24	Mombasa	Mombasa	MMM-Mombasa	Safi	8/9/2018	sales office mmm-Mwembe	7/1/2018	2/8/2019
25	Kilifi	Malindi	Karibu flour mills	Karibu	8/7/2018	Karibu flour outlet-Mikindani	31/06/2018	12/31/2018
26	Kilifi	Malindi	Lola lola industries	Pwani	8/7/2018	lola loa industry town outlet-Malindi	5/15/2018	1/30/2019
27	Kilifi	Malindi	Malindi flour mills	Unga king	8/7/2018	Cereal and general shop-Malindi	5/10/2018	11/30/2018

Appendix III: Questionnaire

Baseline Study on Maize Flour Fortification in Kenya

Date…………………………………….

Industry name:	**Respondent's Name:** **Designation:** **Tel No:** **Email address:**
County:	
Town:	
Year of establishment:	
Interviewer's Name:	

1. How many employees does the company have? (*Tick appropriately*)

1 <5	2 6-10	3 11-30	4 31 -50	5 51- 100	6 101 -500	7 >500

2. Could you segregate them by gender?
   Number of males ☐ Number of females ☐

3. What is the percentage of skilled labour in the factory? (*Tick appropriately*)

1 <10%	2 11-20%	3 21-40%	4 41-60%	5 61-80%	6 81-90%	7 91-100%

4. What type of mill do you use?

Type of Mill	**Installed Capacity (Ton/hr)**	**Actual Production Capacity (Ton /hr)**
1. Hammer Mill		
2. Colloidal Mill		
3. Attrition Mill		
4. Others (specify)		

5. What brands do you produce? Fill in the table below;

Product name	**Fortified** 1. Yes 2. No	**Packaging** 1.Plastics 2.Sacks 3. Kraft paper/khaki 4. Carton boxes 5. Metal 6. Foil	**Do packages have logos?** 1. Yes 2. No	**Specify logo** 1.KEBS 2.Fortification 3.Both 1 &2	**Geographical coverage** 1. District 2.County 3.Region 4.Country 5. International

6. Are your products targeted towards a certain consumer base?
   1. Yes
   2. No

If yes, who? *(Tick appropriately)*

1 Infants	2 School Children	3 Pregnant women	4 Lactating mothers	5 Adults	6 Old	7 Sick	8 Any other (specify)

Premixes

7. Where do you get your premix from?

Source of premix 1. Bio Foods Products Limited 2. Somochem Kenya Limited 3. Chemical & Solvents (EA) 4. Engrain East Africa 5. Remco Africa Ltd 6. Amesi Kenya Ltd 7. Buhler Ltd 8. High Nutrition Limited 9. Imcd Kenya 10. Vital Molecules Ltd 11. Philips Pharmaceuticals 12. Finken Holdings Ltd 14. Own importation 15. Others (specify)	**Unit** 1kg = 1 5kg = 2 10kg = 3 25kg =4 50kg =5 100kg =6 Others (specify) = 7	**Buying price/ unit (Ksh)** 1. Sh.500 - 799 2. Sh.800 - 999 3. Sh. 1000 - 1500 4. Others (specify)

8. How do you store your premixes?

9. What challenges do you experience in acquisition of premixes?
   a)
   b)

c)

Dosers

10. Do you have a doser/feeder?
    1. Yes
    2. No

    If yes?

Brand	**Capacity**	**Cost (Ksh '000')** 1. Sh. 300- 499 2. Sh. 500-799 3. Sh. 800-999 4. Sh.1000- 1500 5. Others (specify)	**Compatible with mill** 1. Yes 2. No

11. How often are the dozers calibrated?
    1. After each batch
    2. Daily
    3. Weekly
    4. Monthly
    5. Quarterly
    6. Bi-annually
    7. Yearly
    8. Others (specify)
12. What is the length of the mixing channel?

13. What are the challenges experienced with dosing?
    a)
    b)
    c)
    d)

Mixers

13. Is your dozer equipped with a mixer?

1. Yes
2. No

If yes?

Brand	Capacity	Cost (Ksh '000') 1. Sh. 50-79 2. Sh. 80-99 3. Sh.100- 150 4. Others (specify)	Compatible with mixer 1. Yes **2.** No

14. What is the length of the mixing channel / duration of mixing?
15. What are the challenges experienced with mixing?
    a)
    b)
    c)
    d)

Training

16. Do you have trained mill operators?
    1. Yes
    2. No

    If yes, how many? *(Tick appropriately)*

1 <5	2 6-10	3 11-30	4 31 -50	5 51- 100	6 101 -500	7 >500

17. How were they trained?
    1. Formal training
    2. Mill owner-supervisor training

3. On job training
4. Online training
5. Others (specify)

18. How many people in mill have undergone any of the following fortification related training?

Type of training	**Trained** 1. Yes 2. No	**Number trained**	**Who organized?**	**When?**
a) Standards for maize flour fortification and regulations in Kenya?				
b) Premix quality and handling (including calculations for addition)				
c) Internal Monitoring (QA/QC)				
d) Calibration of doser and other mill equipment				
e) Any other kind of training undertaken				

19. What other training areas do you think are required for your personnel to support maize flour fortification?

a)
b)
c)
d)
e)

Quality Assurance/Quality Control

20. Do you have a laboratory or QA/QC room?

    1. Yes
    2. No

21. Do you have documented guidelines for QA/QC (Quality Assessment and Quality Control)

    1. Yes
    2. No

22. Do the QA/QC procedures incorporate elements of food fortification? (If mill is already fortifying)

    1. Yes

    2. No

23. What routine tests are done in your lab?

    a)

    b)

24. How often is this done in your lab? *(Internal)*

    1. Hourly
    2. Two hourly
    3. After every batch
    4. Daily
    5. Weekly
    6. Monthly
    7. Quarterly
    8. Semi-annually
    9. Annually (once every year)

25. How long does it take to get your results from your internal QA/QC lab?

(Tick where appropriate)

1 Immediately	2 After an hour	3 After 2-4 hours	4 After 5-6 hours	5 After a day	6 After 2 days	7 1 week	8 1 month

26. Are your samples tested elsewhere? (*External*)

1. Yes
2. No

If yes where………………….

27. What tests are done externally?

a)

b)

c)

d)

28. How often is this done?

1. Weekly
2. Monthly
3. Quarterly
4. Semi-annually
5. Annually (once every year)
6. Others (specify)

29. How long does it take to get the results? *(Tick where appropriate)*

1 < 1 week	2 1 week	3 1 month	4 2 -3 months	5 3- 6 months	6 7 –months -1 year	7 >1 year

30. Is the analysis affordable? *(Tick where appropriate)*

1. Very affordable	2.Affordable	3.Not sure	4.Expensive	5.Very Expensive

31. What quality parameters are checked when maize grain is received

1. Moisture
2. Color
3. Foreign materials
4. Aflatoxin
5. Others (specify)

32. Have you ever been inspected by regulating agencies?
1. Yes
2. No

33. If Yes, by which organization? *(Tick appropriately)*

1. KEBS	2. MOH Public health officers (National/County Government)	3. Ministry of Trade	4. Others, specify

34. How often are you inspected?
    1. Weekly
    2. Monthly
    3. Quarterly
    4. Biannually
    5. Annually
35. Do these organizations give you feedback?
    1. Yes
    2. No
    If yes, after how long? *(Tick appropriately)*

1 < 1 week	2 1 week	3 1 month	4 2 -3 months	5 3- 6 months	6 7 –months -1 year	7 >1 year

36. What are the main challenges relating to fortification compliance?

    a)

    b)

37. What do you think should be done to overcome the challenges?

    a)

    b)

38. How does fortification impact on your profitability?
    1. Very significantly
    2. Significantly
    3. Not sure
    4. Minimal
    5. Very minimal

Appendix IV: Instruments Used for Laboratory Analysis

	HPLC method	**System components**	**HPLC parameters**
1	HPLC (Vitamin /B_3, B_9)	Shimadzu LC-20A (Japan): Pump (LC-20AD) Auto sampler (SIL-20A HT) Column heater (CTO-10ASvp) Photodiode detector (SPD-M20A), Degasser (DGU-20A$_{SR}$) Software: (LCSolution)	**Column:** Phenomenex Luna® 5µm C18 (2) 100 A, LC column 250 x 4.5 mm (Phenomenex, Aschaffenburg, Germany) **Injection volume:** 20 µl **Column temperature:** 25 ^oC **Auto sampler temperature**: room temperature. **Mobile phase:** 10 % methanol and 90 % 0.1M $K_4H_2PO_{4-}$ buffer at pH 7 **Flow pump 1** (isocratic): 0.8 ml/min. **Detector settings**: **SPD-M20A:** 260 nm (Vitamin B_3), 280 nm (Folate)
2	HPLC (Riboflavin)	Shimadzu LC-20A (Japan): Pump (LC-20AD)	**Column:** Phenomenex Luna® 5µm C18 (2) 100 A, LC column 250 x 4.5 mm (Phenomenex, Aschaffenburg, Germany) **Injection volume:** 20 µl

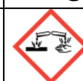
		Auto sampler (SIL-20A HT) Column heater (CTO-10ASvp) Photodiode detector (SPD-M20A), Degasser (DGU-20A$_{SR}$) Software: (LC Solution)	**Column temperature:** 25 ^{o}C **Auto sampler temperature**: room temperature. **Mobile phase:** 40 % methanol and 60 % Acetic acid (2%) **Flow pump 1** (isocratic): 0.8 ml/min. **Detector settings**: **SPD-M20A:** 270 nm
3	HPLC (Retinol)	Shimadzu LC-20A (Japan): Pump (LC-20AD) Auto sampler (SIL-20A HT) Column heater (CTO-10ASvp) Photodiode detector (SPD-M20A), Degasser (DGU-20A$_{SR}$) Software: (LC Solution)	**Column:** Phenomenex Luna® 5µm C18 (2) 100 A, LC column 250 x 4.5 mm (Phenomenex, Aschaffenburg, Germany) **Injection volume:** 20 µl **Column temperature:** 25 ^{o}C **Auto sampler temperature**: room temperature. **Mobile phase:** 95% MeOH (10%) 5% water **Flow pump 1** (isocratic): 1 ml/min. **Detector settings**:

			PDA: 325 nm
4	Atomic Absorption Spectrometer (Zinc)	Hollow Cathode Lamp	
5	Atomic Absorption Spectrometer (Iron)	Hollow Cathode Lamp	
6	Incinerator		
7	Murfle furnace	Advantec KL-420 electric murfle furnace	
8	Desiccator		
9	Analytical balance	HZT-A + 200, Voltage DC12V	
10	Mixer	IWAKI mixer, model-TM-151, No. 68130	
11	Centrifuge	Hettich Zentrifugen, D-78532 Tuttlingen, Germany	
12	Water bath	Memmert WNB 221, 230V-50/60HZ, F-Nr.:L517.0834	
13	Rotary Evaporator	Bibby rotary evaporator RE100, water bath RE100B	

Appendix V: Solvents and Laboratory Chemicals Used

The chemicals and reagents used for nutrient analysis, including safety data information according to the Gobally Harmonised System of Classification and Labelling of Chemicals (GHS) are described in annex 2A and 2B.

Solvent/Chemical	Producer	Acronym	Formula	CAS-no.	Amount	Pictograms	H and P Statements
Methanol (HPLC-LC-MS grade)	RanKem	MeOH	CH_4O	67-56-1	2.5 L	 Danger	H225, H301 + H311 + H331, H370, P210, P240, P280 , P302 + P352, P304 + P340, P308 + P310, P403 + P233
Hexane	Loba Chemie				2.5 L		
Potassium hydroxide	Loba Chemie	Potash caustic	KOH	1316-58-3	500 g	 Danger	H290, H302, H314, P280, P301 + P330 + P331 P305 + P351 + P338, P308 + P310

L (+) ascorbic acid	Sigma Aldrich	Vitamin C	$C_6H_8O_6$	Lot #SZBC1210V	25g	-	-
Acetonitrile (Chromasolv® gradient grade for HPLC)	Sigma Aldrich	2-propanone	CH_3COCH_3	75-05-8	2.5 L	  Danger	H225, H319, H336, P210, P240, P305 + P351 + P338, P403 + P233
Hydrocholic acid			HCL		2.5 L	 Danger	H290, H314, P280, P301 + P330 + P331 P305 + P351 + P338, P308 + P310
Peanut oil							
MilliQ water	Sigma-Aldrich	Deionized water	H_2O	7732-18-5	-	-	-
Glacial acetic acid	Scharlau						
Dipotassium hydrogen phosphate			K_2HPO_4				
Butylated Hydoxytoluene	BHT						

Appendix VI: Working Solutions for Laboratory Analysis

	Reagent/solution	**Concentration**	**Preparation**
2.4.1	Hydrochloric acid (HCl)	0.2 Mol/l	200 ml 1 M HCl were diluted in 800 ml of bidistilled water and filled up to 1000 ml.
2.4.2	Hydrochloric acid (HCl)	0.1 Mol/l	100 ml 1 M HCl were diluted in 900 ml of bidistilled water and filled up to 1000 ml.
2.4.4	Potassium hydroxide	50%	50g potassium hydroxide were dissolved in small amount of deionized water and filled up to 100 ml.
2.4.5	Acetic acid	2 %	20 ml acetic acid were diluted in 980 ml Deionized water to make 1000 ml.
2.4.6	Acidified deionized water	pH 4.5	0.001M HCl was added into a beaker with deionized water dropwise while strirring until the pH was attained
2.4.7	Hexane with 0.01% BHT	0.1% BHT	0.1g of BHT was weighed into 1000ml volumetric flask and made to the mark with hexane

Appendix VII: Standards Used

Micronutrient	Standard used	Producer/supplier	Amount	Product no.	CAS
Zinc	Zinc AAS standard solution 1000mg/l Zn in 0.5M HNO_3	Reacogon	500ml	AAZNH	
Iron	Iron AAS standard solution 1000mg/l Fe in 0.5M HNO_3	Reacogon	500ml	AAFEH17CL	
Vitamin B2	(-)Riboflavin Erenmotheium ashbyli ≥ 98%	Sigma-Aldrich	R4500-25g	#SLBG6534V	
Vitamin B3	Nicotinic acid ≥ 99.5% HPLC	Sigma-Aldrich	2309-100g	#BCBP0239V	59-67-6
Folate	Folic acid ≥ 97% HPLC	Fluka Biochemika	47620-25g		
Vitamin A	Retinol Palmitate	Sigma-Aldrich	R1512-5g	#MKBT1636V	