COMPLIANCE OF FORTIFIED MAIZE FLOUR WITH TANZANIA STANDARD FOR SMALL SCALE FOOD PROCESSORS IN MOROGORO AND DAR ES SALAAM REGIONS

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EXTENDED ABSTRACT

Maize flour fortification was introduced in Tanzania in 2011 in order to address the risk of micronutrients deficiency in children, adolescence and women of child bearing age. Most of fortified maize flours are processed by small scale processors who are exempted from mandatory fortification. They have been carrying out fortification for more than 3 years and it is important to know whether fortification is carried out as per the recommended standards or not. Therefore, the study aimed at assessing the compliance and stability of fortified maize flour processed by small scale processor relative to the recommended national standard (TZS 328:2018- EAS 768:2013), asses the challenges faced by small scale processors to attain compliance and the extent of implementation of fortification practices by small scale processors. A total of sixty-nine (69) samples of fortified maize flour were collected at point of production and retail outlets of Ubungo district in Dar es Salaam region and in Morogoro Municipality in Morogoro region. Micronutrients zinc and iron were analyzed using Microwave Plasma-Atomic Emission Spectrometer and folic acid was analyzed using High Performance Liquid Chromatography. There was a significance variation ($p<0.05$) in mean contents in samples collected from production sites and that of retail outlets with production samples having higher mean contents than retail outlet samples. The mean concentrations of iron, zinc and folic acid of samples collected from production sites were 27.17±1.63 mg/kg, 30.56±2.01 mg/kg and 0.69±0.02 mg/kg respectively, while that of retail outlets were 19.34±0.97 mg/kg, 21.71±1.50 mg/kg and 0.49±0.02 mg/kg for iron, zinc and folic acid respectively. Only 31.6% of the assessed samples from production and 12.9% from retail outlets complied with the recommended national standard. The stability of iron, zinc and folic acid for the fortified maize flour stored at room temperature (20 -32ºC) for six months was 95.8% for iron, 96.9% for zinc and 66.9% for folic acid. The main challenges identified by processors that hindered them to attain compliance include; lack of training on fortification standard and awareness of consumers on fortification. Further investigation on consistency performance of dosifier and consistency of training of workers working in the processing unit on the requirements of fortification standard should be done.

The extent of implementation of fortification practice (quality assurance and quality control) by processors to attain compliance as assessed include; cleaning and sanitation, personnel, written procedures or instructions on QA/QC, control of micronutrient premix, control of flour fortification processes and control of fortified flour. It involved a descriptive cross sectional study which was carried out in 38 small scale processing facilities between December 2019 and January 2020 in Ubungo district in Dar es Salaam region and Morogoro Municipality in Morogoro region. Results indicated that 26.3% of the premix were kept open in production area close to milling machine where heat is generated and only 68.4% of fortified maize flour were stored over the pallet. Furthermore, it was observed that only 2.6% of processors had written instructions or procedures that guide them during fortification process to ensure quality and only 13.2% were able to conduct quality assessment to confirm the presence of micronutrients. It is concluded that implementation of quality assurance and quality control practices by small scale processors is not satisfactory. Strengthening of quality assurance and quality control practices to small scale processors is recommended in order to ensure that the targeted groups of people receive safe and quality fortified maize flour with adequate micronutrients.

DECLARATION

I, Mareni Gudila Boniface do hereby declare to the Senate of Sokoine University of Agriculture that this dissertation is my own original work done within the period of registration and that it has neither been submitted nor being concurrently submitted in any other institution for a degree award.

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DEDICATION

I dedicate this work to my beloved late father Mr. Boniface Mareni who passed away during my study, may his soul continue to rest in peace and my mother Mrs Akulina Boniface for building a strong foundation in my education since my childhood. I also, dedicate this work to my beloved husband, Mr. Wilson Mbuya for his support, encouragement, and constant love and to my lovely children Dylan, Evan and Joan for their love and patience during my absence.

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LIST OF ABBREVIATIONS AND ACRONYMS

ANOVA	Analysis of Variance
CCV	Continuing Calibration Verification
ECSA	East, Central, and Southern Africa
FACT	Fortification Assessment Coverage tools
FAO	Food and Agriculture Organization
FIFO	First In-First Out
GAIN	Global Alliance for Improved Nutrition
HPLC	High Performance Liquid Chromatography
ICV	Initial Calibration Verification
LMIC	Low and Medium Income Countries
MP-AES	Microwave Plasma-Atomic Emission Spectrometer
NaFeEDTA	Sodium iron ethylenediaminetetraacetate
NBS	National Bureau of Statistics
NTDs	Neuro Tube Defects
PHC	Project Healthy Children
PPE	Personal Protective Equipments
QA	Quality Assurance
QC	Quality Control
SADC	Southern African Development Community
SPSS	Statistical Package for Social Sciences
SUA	Sokoine University of Agriculture
TBS	Tanzania Bureau of Standards
TDHS	Tanzania Demographic House Survey
TFDA	Tanzania Food and Drugs Authority
TFNC	Tanzania Food and Nutrition Centre

UNICEF	United Nations International Children's Emergency Fund
UNIDO	United Nations Industrial Development Organization
URT	United Republic of Tanzania
UWAWASE	Umoja wa Wamiliki na Wazalishaji Sembe/dona
WEOs	Ward Executive Officers
WHO	World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

The concern on micronutrients malnutrition is a global problem which greatly affects large population especially in the developing countries (Dary and Mora, 2002). This is manifested by approximately two billion people worldwide suffering from diseases related to micronutrient deficiency (Baye, 2019). This deficiency is caused by insufficient intake of micronutrients or impaired absorption of consumed micronutrient due to disease(s) or infection (Nandagopal and Danisha, 2018). The human body is unable to synthesize these micronutrients and small amount is needed for different body functions including normal growth, birth weight, cognitive development, cellular functioning and immune system functioning (Burchi *et al.*, 2011; Abeshu and Geleta, 2016). Iron, zinc, folic acid, vitamin B12, vitamin A and iodine are the mostly micronutrients needed by the body and lack of them has been identified by WHO as the most world's serious health risk (Nandagopal and Danisha, 2018). The most affected populations with micronutrients deficiency are reproductive aged women, young children and female adolescents particularly in Low and Medium Income Countries (LMIC) (Osendarp *et al*., 2015). To alleviate this problem, WHO (2006), identified nutrition education leading to increased diversity and quality of diets, food fortification and bio-fortification, supplementation, and disease control measures as main strategies for addressing micronutrient malnutrition. Food fortification has been declared as one of the proper approach to reach the targeted group of people without changing the existing pattern of food delivery (Baye, 2019).

Globally, many countries had set up fortification of different food such as salt, margarine and vegetable oil, sugar and cereal crops. Mandatory iodization of salt is now practiced by 140 countries (WHO, 2014) while fortification of cereal crops with folic acid is implemented by 85 countries. Also mandatory fortification of edible oil with vitamin A and/or D has been also implemented by more than 40 countries (Hoogendoorn *et al.,* 2016). Government of Tanzania officially introduced mandatory fortification of vegetable oil, maize and wheat flour in 2011, requiring all processed maize flour at large scale be fortified with iron, zinc, folic acid and B12 and all manufacturers of fortified food should operate within limits set by the government to ensure food is properly fortified as poor compliance with laws and regulations limits potential for impact and weakens efficiency of fortification (Noor *et al.,* 2017).

1.2 Problem Justification

According to the national nutrition social and behavior change communication strategy of July 2013 – June, 2018 children of Tanzania continue to suffer from one or more forms of under nutrition, including low birth weight, stunting, underweight, wasting, anemia, iodine and vitamin A deficiency (URT, 2016), where by underweight contributes 22% and stunting contributes 34% (TFNC, 2014; UNICEF, 2019). This is a burden to the economy of the country. Each year deficiency of iron, vitamin A and folic acid cost the country over US$ 518 million which is around 2.65 % of the country's Gross Domestic Product (GDP). Also micronutrients deficiency causes a significant mortality, with over 27,000 infant death and 1,600 maternal deaths annually (Noor *et al.,* 2017).

Maize in form of maize flour is mostly consumed in Tanzania whereby 50 to 80% of the total energy of the food consumed comes from maize (Kavishe and Harris, 2017). During processing of maize to maize flour which involves dehulling and degerming some of micronutrients are lost. Therefore, the government of Tanzania introduced mandatory fortification for large scale processors of fortified maize flour in 2011, whereby maize flour is fortified with zinc, iron, folic acid and vitamin B12 in order to combat micronutrients deficiency. However, most of the consumed fortified maize flour in the market is processed by small scale processors who are exempted from mandatory fortification and the compliance of this small scale processors to the recommended national standard to make sure the targeted group of people consumed adequate micronutrients have not been studied. Also the compliance of fortified food in LMIC countries Tanzania inclusive were found to be around 40% where by non-compliance food were labelled as compliant which misled consumers on micronutrients contents of the food (Darnton-Hill *et al.,* 2017). Therefore, this study assessed the compliance of fortified maize flour processed by different small scale processors to the recommended national standard (TZS 328-2: 2018- EAS 768: 2013) in Morogoro and Dar es regions, Tanzania.

1.3 Objectives

1.3.1 Main objective

The main objective of this study was to assess the compliance of domestic processed fortified maize flour with national standard in Dar-es salaam and Morogoro regions.

1.3.2 Specific objectives

The specific objectives of this study were:

i. To determine the extent to which micronutrients of fortified maize flour (Iron, zinc and folic acid) comply with national and regional standard

ii. To assess the compliance of the selected small scale processors of fortified maize flour with fortification practices (quality assurance and quality control).

iii. To determine effect of storage on the level of iron, zinc and folic acid in the fortified maize flour.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Micronutrients Malnutrition

Vitamins and minerals are the micronutrients needed by the body and its deficiency which is known as micronutrients malnutrition has been identified as a global problem (Sibhatu and Qaim, 2017). Its deficiency is also known as a hidden hunger due to lack of the clinical symptoms and its signs being less visible by our normal sense compared to other forms of malnutrition (Tulchinsky, 2010). There are numbers of factors which contributes to this deficiency including; consumption of food lacking micronutrients or poor bioavailability of consumed food due to presence of inhibitor or diseases, increased consumption of nutrients by fetus during pregnancy (WHO, 2006; Motadi, 2016). For the proper function of the body, these micronutrients are needed in small amount and its deficiency in the body causes a number of diseases such as goiter, blindness, anemia, wasting, neuro tube defect, stunting growth, low birth weight, morbidity and mortality (Berti, *et al.*, 2014; Burchi *et al.*, 2011). It is estimated that, up to 2011, about 6.9 million children under 5 years of age died worldwide with the highest rate in Sub-saharan Africa having a death of 1 in 9 children (UNICEF, 2012).

Despite of the initiatives which have been taken by the government of Tanzania to combat micronutrients malnutrition, the case is still burden in the country whereby 22% and 34% of children are underweight and stunting, respectively (TFNC, 2014 and UNICEF, 2019). Also 41% of reproductive aged (15-49) Tanzanian women are anemic and 30% have iron deficiency. Children with iron deficiency are 35% while the one with iron deficient with anemia is 59%. The prevalence of iron deficiency is high in children aged 6-11years and 12 – 23 months (NBS and ICF Macro, 2011) due to low consumption food rich in micronutrients. According to the state of world’s Children report of 2019, 29% of

Tanzanian children aged 6 -23 months were found to consume neither vegetables nor fruits which is among the causes of increase in micronutrients deficiency (UNICEF, 2019).

2.2 Strategies to reduce micronutrients malnutrition

Many strategies have been in place to save people from micronutrients deficiency. Nutritional education on consumption of different variety of food and balanced diet, food fortification and bio fortification, supplementation and diseases control measures have been acknowledged by WHO as measure to eradicate these deficiencies (WHO, 2006). Fortification of different selected staple food was found to be the best approach to reach mass of targeted people without interfering the existing mode of feeding, or cooking habits (Baye, 2019; Abeshu and Geleta, 2016). To implement food fortification, an individual country should establish the type of staple food to be used in fortification, its availability through the year (Fathima *et al.,* 2017), the required micronutrients level based on the level of risk population, climatic condition, packaging materials and storage time (Dary and Hurrell, 2006).

2.3 Global food fortification

Fortification is the practice of deliberately enriching food for the purpose of improving nutritional quality by adding one or more micronutrients (Dary and Hurrell, 2006). It has been practiced by the developed countries in several decade (Dary and Mora, 2002), starting with salt iodization in USA in 1920 after finding that, goiter in school children can be prevented by iodine (Bishai and Nalubola, 2002). Following this development, in 1922 Switzerland implemented table salt iodization (Hess, *et al.,* 2001). Mandatory fortification practices of flour with vitamin A and B were extended in USA in 1944 due to massive of people who lost their lives due to pellagra and the introduction of mandatory fortification of flour with niacin in Mississippi resulted in reduction of pellagra from 101 to 1 in every 100,000 lives within one year (Humphreys, 2009). Also fortification of polished rise in Philippines resulted in reduction of death caused by lack of vitamin B by 69% (Liberato and Pinheiro-Sant'Ana, 2006). From there fortification of other product with different micronutrients were evolved and margarine was fortified with vitamin A in Denmark (Jacobsen *et al.* 2015), USA and Canada extend their fortification program by enriching milk with vitamin D to combat rickets problems in infants and young children (Calvo *et al.*, 2004).

2.4 Food fortification in Africa

Micronutrients malnutrition is still high in developing countries including Africa due to food insecurity (Berti *et al.* 2014) and consumption of food which lack vitamin and minerals like meat and meat products, fruits and vegetables. Poverty led most of Africans to consume products like roots and tubes which are low rich in micronutrients (Miller and Welch, 2013) and refined cereal products such as rice, maize and wheat flour of which most of its inherent micronutrients have been diminished in the cause of processing (WHO, 2006). This increases the burden of micronutrient deficiency in reproductive women, adolescence and under five children (Enzama *et al.*, 2017). These group of people are mostly affected by deficiency of iron, zinc, vitamin A, folic acid and B_{12} (Method and Tulchinsky, 2015) and increase cases of morbidity and mortality in under five children, women of age bearing and pregnant mother. Iron deficiency, the one causative of anemia is mostly affected pregnant women and under five children with the prevalence of 42% to 53% respectively (Enzama *et al.*, 2017). According to TDHS, (2010) more than one third (39%) of reproductive African women aged 15-49 year are anemic due to iron deficiency (NBS and ICF Macro, 2011).

Adoption of fortification practices was done in different African countries for the past years. In 1990 salts iodization was introduced in East, Central, and Southern Africa (ECSA) regions and have extended to more than 50 African countries (Jooste e*t al.*, 2013). Fortification can be voluntary or mandatory. Mandatory fortification is the best practice as the processors of fortified food is bounded by the laws and regulation of the country to make sure the products are adequately fortified. According regional consultative and capacity building workshop conducted in South Africa in October 2018, mandatory fortification of wheat and or maize flour is practiced among SADC regions, Malawi, Mozambique, South Africa, Tanzania, and Zimbabwe while Botswana, Democratic Republic of the Congo, Lesotho, Namibia, Eswatini, and Zambia practiced voluntary fortification. The persisting problems of micronutrients deficiencies make some of African countries to unite and find a solution to combat the problem as whole. In 2016 more than 10 African countries met in Dar-es Salaam to discuss strategies of scaling up maize flour fortification which is voluntary in many African countries except few. The developed strategies were used as basis for individual country to develop national maize flour fortification strategies (Enzama *et al.*, 2017).

2.5 Food Fortification in Tanzania

Food fortification was introduced in Tanzania since 1990s starting with universal salts iodization due to persistence of goiter resulted from inadequate consumption of iodine. This help to reduce a total goiter from 61% in 1980s to 12.3% in 2004 (Assey *et al.*, 2009). Also Tanzania extended coverage range of fortification programme for other staples product such as maize flour, wheat flour and vegetable oil (Smith *et al.*, 2006) in order to intervene other forms of micronutrients deficiencies by developing fortification procedures and policies in the period of 2001 to 2009. This was done by joint committee consisting of staff from broader micronutrients and health program (MICAH), ministry of health, Universities, NGOs, and other technical expertise (Mildon *et al.*, 2015). The established policy passed on 2011 and the government of Tanzania announced it as mandatory for vegetable oil, maize and wheat flour. However, small scale processors of fortified maize flour were exempted from this mandatory fortification since the existing regulatory requirement had not been adhered by them (Mildon *et al.*, 2015; Bymolt and d'Anjou, 2017). Currently vegetable oil is fortified with vitamin A, maize and wheat flour are fortified by iron, zinc, folic acid and vitamin B12 (Noor *et al.*, 2017).

2.6 Maize flour fortified with zinc, iron, folic acid and vitamin B12 in Tanzania

Maize (*Zea mays L.*) is a type of cereal produced worldwide and mostly used for human consumption, feed for livestock and raw material for industry (Gwirtz and Garcia-Casal, 2014). About 3.5 million small farmers cultivated maize and most of family depends on it as the main meal which makes it to be an important crops in Tanzania as well as staple crops (Wilson and Lewis, 2015). Depending on meal preparation, consumption of maize can be as whole or in processed form. In Tanzania mainland maize consumption account for 1164 kcal/d which is about 50 - 80% of energy intake for the food consumed, indicating that fortification of maize flour will reach a large proportion of the population. (Kavishe *et al.*, 2017; Suri and Tanumihardjo, 2016).

Whole maize is processed to maize flour by millers and used in preparation of different dishes like 'ugali' and 'uji' which provide at least half of the daily requirement of calcium, iron, and zinc due to the fact that large amount is reduced during processing. Naturally whole maize contains different micronutrients like phosphorus, calcium, potassium, iron, zinc, folate, riboflavin, thiamin, niacin of which iron account for 27 mg/kg, zinc is 22.1 mg/kg and folate account for 0.19 mg/kg (Suri and Tanumihardjo, 2016). The milling process of maize to maize flour which involve dehulling and degumming tends to lessen some of micronutrients and fortification is the proper way of retaining the lost one (Peña-Rosas *et al.,* 2014). In Tanzania maize flour is fortified with multiple micronutrients which are sodium iron ethylenedi-aminetetraacetic acetate (NaFeEDTA), folic acid, zinc oxide and vitamin B12 to enrich it with vitamin and minerals (Kavishe *et al.,* 2017) whereby manufacturers of fortified maize flour are required to conform to national fortification standard (TZS, 2018) for quality and safety of the product.

Tanzania has a number of small scale maize millers around 95% which are scattered in villages and urban areas (Bymolt and d'Anjou, 2017) and feed majority of people in the surrounding area. Manzese and Tandale in Dar es Salaam as well as Morogoro municipality are characterized by having many small scale millers. According to report from maize fortification strategy workshop on 2016, most of these millers operate commercially by packing their own maize flour in branded bags and sell it to local shops, schools, institutions and individual customers while other millers serve client who come with their own maize to be processed at the mill (World Bank, 2012).

In order to increase the coverage of fortified maize flour the government run a project known as Millers Pride – Lishe Bora' 2013 to 2016 to support these small scale millers in fortification process. The project organized millers in Tandale and Manzese by forming association known as UWAWASE group. Through this and with support from the former Tanzania Food and Drug Authority (TFDA), Tanzania Food and Nutrition Centre (TFNC) and Ministry of Agriculture, Food and Cooperative the project successfully trained millers in GMP, food safety and hygiene, nutrition and maize fortification procedures (Bymolt and d'Anjou, 2017). Maize flour fortification is done using multiple micronutrients which are iron, zinc, folic acids and vitamin B12 in order to combat micronutrients deficiency in population. For small scale processors fortification is done by using SANKU dosifier which is installed in the hummer mill and automatically dispense premix in the flour during milling based on the milling speed thereby reducing possible human error (Bymolt and d'Anjou, 2017).

2.6.1 Iron

Iron is micronutrient essential for a wide variety of biological body functions. It can be obtained from both plants and animal sources. The one from animal source is called heme where as those found in plant and those used during fortification is called non-heme (Bailey, 2015). The body needs iron for the synthesis of hemoglobin for different body functions and consumption of food rich in low micronutrients such as iron result to nutritional anemia (NBS and ICF Macro, 2011). Also most enzymatic processes essential for fetus brain development, oxygen transport via hemoglobin and immune response depends on iron (Sarkar *et al.,* 2018). Long term negative iron balance in the body due to progressively diminish of the stored hemosiderin and ferritin and consumption of diet which does not meet body's requirements leads to iron deficiency (anemia) (Camaschella, 2019).

on deficiency results when either dietary intake does not meet the body's requirement or when there is chronic external (non-resorptive) blood lo

Iron deficiency and associated health effects

Lack of iron disrupt body's function both endocrine and immune system. Iron is the most micronutrient in the world that cause anemia and it is estimated to contribute 20% of maternal deaths (Bailey, 2015). During fetus growth and development iron is needed in large amount which may result to maternal iron deficiency if adequate amount of iron is not consumed by the pregnant woman (Miller, 2013). Iron deficiency is also associated with low birth weight, premature delivery and perinatal complication, intrauterine growth restriction (Bailey, 2015). Iron deficiency (ID) with anemia or iron deficiency without anemia is estimated to affect about two billion people globally (Al-alimi Abdullah Ahmed *et al.,* 2018; Mildon *et al.,* 2015). This result in reduced psychomotor and mental development in infant (Stoltzfus *et al.,* 2004), adverse pregnancy outcome, premature delivery and decreased immune function. Having iron deficiency with anemia, my also result to body weakness, fatigue, difficult in concentration and poor work productivity due to low supply of oxygen in body tissues (Camaschella, 2015).

The study conducted in Tanzania revealed that 40% of reproductive age women are anemic of which less than one in three of rural mother consume iron-rich foods per day (NBS and ICF Macro, 2011). This is estimated to contribute one death in five women during pregnancy (Robinson and Nyagaya, 2014). Also it was estimated that six in every ten children which is equal to 58% of Tanzania mainland are anemic (NBS and ICF Macro, 2011).

2.6.2 Folic acid

Folic acid is a water soluble B9 - vitamin that is synthetically produced and is full oxidized monoglutamate form of folate (Field and Stover, 2018). Folate is naturally found in a variety of food including plant and vegetables such as dark leafy greens, broccoli, asparagus, avocado, peas and lentils. It is also found in meat products such as chicken and turkey (Liew, 2016; Centeno *et al.,* 2019). It can be found in fortified foods such as cereal, pasta, flour, grains and bread and in supplement. Folate has a major importance in the body during cell division (replication of DNA and RNA) and it is responsible in nucleotides synthesis and tissue growth (Mahmood, 2014).

Folate deficiency and associated health effect

Inadequate consumption of folate high rich food such as green leaf and vegetables as well as adequate consumption of refined cereals contributes to folate deficiency (WHO, 2006). Lack of folate in the body may lead in weight loss, slow growth in children, and in severe cases megaloblastic anemia. Also inefficient folate contributes to an increase the rate of Neuro Tube Defects (NTDs) in pregnant human (Crider *et al.*, 2013), which is the brain and spine defect that occurs early in pregnancy due to improper closure of the embryonic neural tube and contribute to death and or varying degrees of disability (Williams, *et al.*, 2015). High consumption of folic acid in the fortified food increases the blood folate concentration and reduces the risk of NTDs in pregnancy women (Marchetta *et al.*, 2015; Osendarp *et al.,* 2018). The study conducted by Kishimba, *et al.* (2015) in Muhimbili National Hospital, Temeke, Mwananyamala and Amana hospitals revealed that 9.9 per 10,000 live births had neuro tube defect.

2.6.3 Zinc

Zinc is a trace element in which all catalytic, structural and regulatory function of the body such as protein synthesis, cellular growth, and cellular differentiation depends on it (Kujinga-Chopera, 2016, Bierens and Van Bockstaele, 2017). Zinc is largely found in meat, fish and shellfish, nuts, seeds, legumes, and wholegrain cereals (Shah *et al*., 2016). In its biochemical role zinc acts as cofactor on metallo-enzyme active site (Al Mamun and Ghani, 2017). Also factor responsible for regulation of gene expression depends on zinc during stimulation as a result numerous biologic functions, a deficiency state will affect a number of biochemical pathways thus disrupting multiple functions in the body (Kujinga-Chopera, 2016).

Zinc deficiency and associated health effects

Zinc deficiency varies from one person to another depending on age (Shah *et al.*, 2016). Inadequate zinc consumption may cause growth retardation, impair cognitive function in children (Al Mamun and Ghani, 2017), diarrhea and recurrent infections (Lazzerini and Ronfani, 2013), delayed sexual and bone maturation, skin lesions and increased susceptibility to infections mediated via defects in the immune system (Chasapis *et al.*, 2011). It also results in impairment of reproductive performance in adolescents and adult as well as repeated infection in elderly (Kawade, 2012). Many studied have reported high risk of zinc deficiencies in infant and under five children. About 800,000 deaths globally in under five children caused by diarrhea, pneumonia, and malaria is due to zinc deficiency (Bierens and Van Bockstaele, 2017). Also consumption of zinc during diarrhea helps to restore mucosal barrier integrity and enterocyte brush-border enzyme activity and it promotes the production of antibodies and circulating lymphocytes against intestinal pathogen (Lazzerini and Wanzira, 2016).

2.7 Premix requirements for fortification of maize flour

During fortification, the amount of premix to be added in maize flour is subject to the targeted population who are at risk, the amount to be consumed and epidemilogical differences in different countries (Dary and Hainsworth, 2008). The recommended amount of micronutrients to be added in maize flour accourding to WHO is as per Table 2.1.

Table 2. 1: Requirements for micronutrients in fortified maize flour as per WHO

	Nutrient concentration to be added by estimated availability/consumption (mg

Nutrient	Fortificant compounds	nutrient/kg maize flour) Minimum (mg/kg)	Maximum (mg/kg)
Iron	Sodium Iron EDTA	40	40
Zinc	Zinc oxide	95	100
Vitamin B12 0.1% WS	Vitamin B12	0.04	0.04
Folate	Folic acid	5	6

Source: (WHO, 2016) maize flour fortification guideline

In Tanzania the amount of micronutrients to be added in maize flour should comply with the requirements of national standard as shown in Table 2.2. During preparation, the fortificant should be mixed with diluent or carrier as appropriates to form premix in such a way that the product should conform to the required standard during addition (TZS, 2018).

The cost of fortification is high due to premix price and fortificant instruments. In order to reduce burden of fortification to small scale processors, government of the united republic of Tanzania exempted tax for all imported premix. Also in order to motivate the small scale millers to fortify maize flour, SANKU supplied premix to millers in exchange of printed packaging materials for fortified maize flour (Bymolt and d'Anjou, 2017).

Table 2. 2: Requirements for micronutrients in fortified milled maize flour as per Tanzanian standards

Nutrient	Fortificant compounds	Recommended factory level mg/kg	Regulatory level (mg/kg)	
			Minimum	Maximum
Total Iron	Sodium Iron EDTA	31±10	21	41
Zinc	Zinc oxide	49±16	33	65
Vitamin B12 0.1% WS	Vitamin B12	0.015±0.007	0.0007	NA
Folate	Folic acid	1.2±0.5	0.6	1.7

Source:Tanzania Bureau of Standards TZS, (2018)

2.8 Stability of micronutrients in fortified maize flour

For effective fortification impact to be achieved, it is essential to ensure that the food vehicle consistently supplies adequate amounts of nutrients at the point of consumption to the at-risk groups (Florence and Tola, 2016). According to TZS, (2018) the fortificant and premix should have storage stability such that no more than 20% of its origin activity will be lost when stored for 21 days at 45^0C in well closed container at level of 2.5 g/kg in a milled maize product having moisture in the range of 13.5% to 14.5%. The efficiency of the program depends on the safety of the fortification process, stability and acceptability of the product by the target population (Enzama *et al.,* 2017). The stability of micronutrients may be affected by many factors including uncontrolled conditions during storage and transport, long storage times, composition of the micronutrient premix, and interaction between components of the premix (Dunn *et al.,* 2013). Also uncontrolled manufacturing process may lead to excessive or low level of nutrients in the finished products which may affect consumer’s health and the purpose of fortification.

2.9 Quality control and quality assurance

Fortification program need to be monitored in order to ensure quality and consistency product are distributed to the market. To attain the quality product, need the whole chain to be monitored from raw materials to the final consumer. It is the responsibility of processor to make sure that the final products contain the desired micronutrients by controlling the production process to ensure quality assurance and quality control processes are adhered (Wirth *et al.,* 2013). This helps to identify the critical control points where quality of fortified food product might be compromised such as during production due to inadequate mixing of the food and premix or during distribution due to improper storage (Van den Wijngaart *et al.*, 2013). Quality assurance involve varieties of activities such as installation of dosifier, feeder calibration and verification, premix procurement and storage, certificate of quality for premix, use of FIFO i.e. first in, first out, adequate package, process control, laboratory analysis, labelling and storage of final product (Philar *et al.,* 2005; WHO, 2011). Quality control involves activities related to analytical testing to detect, evaluate and correct errors due to test system failure, environmental conditions or operator performance before results are reported. Internal monitoring of fortified food requires a well-documented system such as GMP and HACCP of which most of small scale processors find difficult to implement it due to lack of technical capability, low capital to employ qualified staff, installation of laboratory and modern equipment (WHO, 2011).

In order to ensure that the dosing of the micronutrient premix is properly conducted, internal (i.e., conducted by millers) quality assurance (QA) processes and quality control (QC) tests are employed during production. QA/QC processes and tests

related to fortification verify that fortification is properly implemented and identify any irregularities in
the dosing and mixture of the micronutrient pre

2.10 Compliance of fortified maize flour

For consumers to receive the desired fortified products the manufacturers have to comply with the laws, regulations, guidelines or standards set by the government to ensure the final product contains micronutrients in line with required standard(s) (GAIN and PHC, 2018). Depending on the country regulation fortification can be mandatory or voluntary. With voluntary fortification the processor is free to choose whether to do fortification or not but in mandatory fortification the processor is bounded by the laws and regulations to make sure the processed product is adequately fortified (GAIN and PHC, 2018; Berti *et al.*, 2014).

Compliance of fortified products is still a problem in African countries despite of implementation of mandatory fortification. The study conducted in Nigeria reported compliance level of iron in fortified flour at a range of 1% - 21% (Ogunmoyela *et al.*, 2013). Also, the percentage of compliance of food fortification programme conducted in 25 countries was found to range between 18% to 97% whereby food was found labelled as fortified while the product does not contain the required micronutrients (Garrett and Luthringer, 2015; Van den Wijngaart, 2013). The compliance of fortified food in ECSA countries were found to be low whereby among the identified contributor of noncompliance were lack of quality control and quality assurance at production level and limited testing capacity to confirm compliance (ECSA, 2016).

REFERENCES

Abeshu, M. A. and Geleta, B. (2016). The Role of fortification and supplementation in mitigating the 'hidden hunger'. *Journal of Nutrition and Food Sciences* 6 (1): 459.

Al-alimi Abdullah Ahmed, Bashanfer, S. and Morish, M. A. (2018). Prevalence of Iron Deficiency Anemia among University Students in Hodeida Province, Yemen *Anemia.* 1–7.

Al Mamun, M. A. A. and Ghani, R. B. A. (2017). The role of iron and zinc in cognitive development of children. *Asian Journal of Medical and Biological Research* 3(2): 145-151.

Assey, V. D., Peterson, S., Kimboka, S., Ngemera, D., Mgoba, C., Ruhiye, D. M. and Tylleskär, T. (2009). Tanzania national survey on iodine deficiency: impact after twelve years of salt iodation. *BMC Public Health* 9(1): 319.

Bailey, L. (2015). deficiencies often occur as part of an intergenerational cycle, the Epidemiology of Global Micronutrient. *Deficiencies The Epidemiology of Global Micronutrient* 66(2): 22–33.

Baye, K. (2019). Maximizing benefits and minimizing adverse effects of micronutrient interventions in low and middle income countries. *Proceedings of the Nutrition Society* 78(4): 1–7.

Berti, C., Faber, M. and Smuts, M. (2014). Prevention and control of micronutrient deficiencies in developing countries: current perspectives. *Nutrition and Dietary Supplements* 6: 41–57

Bierens, L. and Van Bockstaele, F. (2017). Impact of fortification on the technological properties of maize meal. Unpublished Dissertation for Award of MSc Degree at University of Ghent, Belgium, pp. 1 – 62.

Bishai, D. and Nalubola, R. (2002). The history of food fortification in the United States: its relevance for current fortification efforts in developing countries. *Economic Development and Cultural Change* 51(1): 37-53.

Burchi, F., Fanzo, J. and Frison, E. (2011). The Role of Food and Nutrition System Approaches in Tackling Hidden Hunger. *International Journal of Environmental Research and Public Health* 8(2): 358–373.

Bymolt, R. and d'Anjou, J. (2017). Lessons on small and medium-scale maize flour fortification in Tanzania: Lessons learned from the Millers Pride – Lishe Bora project. (https://www.wvi.org/sites/default/files/Millers%20Pride%20DSM%20Tanzania.pdf) site visited on 20/10/2018.

Chasapis, C. T., Loutsidou, A. C., Spiliopoulou, C. A. and Stefanidou, M. E. (2011). Zinc and human health: an update. *Archives of toxicology* 86(4): 521–534.

Calvo, M. S., Whiting, S. J. and Barton, C. N. (2004). Vitamin D fortification in the United States and Canada: current status and data needs. *The American Journal of Clinical Nutrition* 80(6): 1710S–1716S.

Camaschella, C. (2019). Iron deficiency. Iron metabolites and its disorders. *Blood.* 133(1): 30-39.

Camaschella, C. (2015). Iron-deficiency anemia. *New England journal of medicine* 372(19): 1832-1843.

Centeno Tablante, E., Pachón, H., Guetterman, H. M. and Finkelstein, J. L. (2019). Fortification of wheat and maize flour with folic acid for population health outcomes. *Cochrane Database of Systematic Reviews* 7: 1-92.

Crider, K. S., Cordero, A. M., Qi, Y. P., Mulinare, J., Dowling, N. F. and Berry, R. J. (2013). Prenatal folic acid and risk of asthma in children : a systematic review and meta analysis. *The American Journal of Clinical Nutrition* 98(5): 1272–1281.

Darnton-Hill, I., Neufeld, L., Vossenaar, M., Osendarp, S. and Martinez, H. (2017). Large-scale food fortification: an overview of trends and challenges in low- and middle-income countries. In Micronutrients Forum. (https://micronutrient forum.org/content/userfiles/2017/01/2017-01-25MNForumfortification report-Updated.pdf) site visited on 16/07/2019.

Dary, O. and Hainsworth, M. (2008). The food fortification formulator. Technical determination of fortification levels and standards for mass fortification. USAID Micronutrient Project, Washington, DC, April, 2008. 29pp.

Dary, O. and Hurrell, R. (2006). Guidelines on food fortification with micronutrients. World Health Organization, Food and Agricultural Organization of the United Nations: Geneva, Switzerland. (http://www.fao.org/3/X5244e04.htm) site visited on 12/03/2020.

Dary, O. and Mora, J. O. (2002). Food fortification to reduce vitamin A deficiency: International Vitamin A Consultative Group recommendations. *The Journal of nutrition* 132(9): 2927S-2933S.

Dunn, M. L., Jain, V. and Klein, B. P. (2013). Stability of key micronutrients added to fortified maize flours and corn meal. *Annals of the New York Academy of Sciences* 1312(1): 15-25.

ECSA, (2016). Harmonization of food fortification inspection guidelines in the East, Central and Southern Africa health community. Proceeding of ECSA workshop, Entebbe, Uganda 7-10, November, 2016. 24pp.

Enzama, W., Afidra, R., Johnson, Q. and Verster, A. (2017). Africa Maize Fortification Strategy 2017-2026. Smarter Futures. (http://ffinetwork.org/regionalactivity/ images/Africa maize strategy2017.pdf) site visited on 1/05/2019.

Fathima, S. J., Nallamuthu, I. and Khanum, F. (2017). Vitamins and minerals fortification using nanotechnology: bioavailability and Recommended Daily Allowances. *In Nutrient Delivery* 457-496.

Field, M. S. and Stover, P. J. (2018). Safety of folic acid. *Annals of the New York Academy of Sciences* 1414(1): 59–71.

Florence, N. U. and Tola, A. (2016). Vitamin A stability in Nigerian wheat flour and fortification compliance level. *African Journal of Food Science* 10(3): 33–40.

Garrett, S. and Luthringer, C. (2015). The Urgent Need to Improve Compliance of National Fortification Programmes. The Global Nutrition Reports. (https://globalnutritionreport.org/blog/urgent need improve compliance national fortification programmes/) site visited on 17/3/2020.

Gwirtz, J. A. and 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.

GAIN and Project PHC, (2018). Regulatory monitoring of national food fortification programs: A policy guidance document. Global Fortification Technical Advisory Group (GF-TAG). (https://www.gainhealth. org/ sites/ default/ files/ publications/documents/regulatory monitoring policy guidance doc.pdf) site visited on 11/06/2020.

Hess, S., Zimmermann, M., Torresani, T., Bürgi, H. and Hurrell, R. (2001). Monitoring the adequacy of salt iodization in Switzerland: a national study of school children and pregnant women. *European Journal of Clinical Nutrition* 55(3): 162–166.

Hoogendoorn A, Luthringer C, Parvanta I, Garrett G. (2016). Food Fortification Global Mapping Study 2016. Technical Assistance for Strengthening Capacities in Food Fortification. European Commission. (https://ec. europa. eu/europeaid/ sites/ devco/files/global-mapping study 2016.pdf) site visited on 20/05/2019.

Humphreys, M. (2009). How four once common diseases were eliminated from the American South? *Health Affairs* 28(6): 1734-1744.

Jacobsen, R., Hypponen, E., Sørensen, T. I., Vaag, A. A. and Heitmann, B. L. (2015). Gestational and early infancy exposure to margarine fortified with vitamin d through a national danish programme and the risk of type 1 diabetes. The D-tect study. *Proceedings of the National Academy of Sciences of the United States of America* 10(6): 1-11.

Jooste, P., Andersson, M. and Assey, V. (2013). Iodine nutrition in Africa: Where are we in 2013? iodine deficiency disorders (IDD) Newsletter, (4): 3-4.

Kavishe, F. P. and Harris, A. (2017). Report on Tanzania's first national summit on food fortification in Tanzania 2017. In: Proceedings of the revisiting commitments from the 2015 Arusha summit. 23-24, August 2017, Arusha Tanzania, pp. 40.

Kawade, R. (2012). Zinc status and its association with the health of adolescence. A review of studies in India. *Global health action* 5(1): 7353.

Kishimba, S. R., Mpembeni, R., Mghamba, M. J., Goodman, D. and Valencia, D (2015). Birth prevalence of selected external structural birth defects at four hospitals in Dar es Salaam, Tanzania, 2011–2012. *Journal Global Health* 5(2): 1-6

Kujinga-Chopera, P. (2016). Effectiveness of zinc fortified drinking water on zinc intake, status and morbidity of rural Kenyan pre-school children Doctoral dissertation, Wageningen University, Wageningen, 138pp.

Lazzerini, M., and Wanzira, H. (2016). Oral zinc for treating diarrhoea in children. *Cochrane Database of Systematic Reviews,* (12): 130pp.

Lazzerini, M. and Ronfani, L. (2013). Oral zinc for treating diarrhoea in children. *Cochrane Database of Systematic Reviews,* (1): 107pp.

Liberato, S. C. and Pinheiro-Sant'Ana, H. M. (2006). Fortification of industrialized foods with vitamins. *Revista de Nutrição* 19(2): 215–231.

Liew, S. C. (2016). Folic acid and diseases supplement it or not? *Revista da associação médica brasileira* 62(1): 90–100.

Mahmood, L. (2014). The metabolic processes of folic acid and Vitamin B12 deficiency. *Journal of Health Research and Reviews* 1(1): 5-9.

Marchetta, C. M., Devine, O. J., Crider, K. S., Tsang, B. L., Cordero, A. M., Qi, Y. P. and Hamner, H. C. (2015). Assessing the association between natural food folate intake and blood folate concentrations: A systematic review and Bayesian meta-analysis of trials and observational studies. *Nutrients* 7(4): 2663–2686.

Method, A. and Tulchinsky, T. H. (2015). Commentary: Food fortification: African countries can make more progress. *Advanced Food Technology Nutrition Science Open Journal* SE (1): S22-S28.

Miller, D. D. and Welch, R. M. (2013). Food system strategies for preventing micronutrient malnutrition. *Food policy* 42: 115-128.

Miller, J. L. (2013). Iron deficiency anemia: A common and curable disease. *Cold Spring Harbor perspectives in medicine* 3(7): 1-13.

Mildon, A., Klaas, N., O'Leary, M. and Yiannakis, M. (2015). Can Fortification be Implemented in Rural African Communities Where Micronutrient Deficiencies are Greatest? Lessons from Projects in Malawi, Tanzania, and Senegal. *Food and Nutrition Bulletin* 36(1): 3–13.

Motadi, S. A., Mbhatsani, V. and Shilote, K. O. (2016). Food fortification knowledge in women of child-bearing age at Nkowankowa Township in Mopani District, Limpopo Province, South Africa. *African journal of primary health care and family medicine* 8(2): 1-5.

Nandagopal, A. and Danisha, S. M. (2018). Fortification: A key role in Micronutrient Deficiency. *Asian Journal of Pharmacy and Pharmacology* 4(2): 109–115.

NBS and ICF Macro (2011). Micronutrients: Results of the 2010 Tanzania Demographic and Health Survey. Dar es Salaam, Tanzania, 63pp.

Noor, R. A., Abioye, A. I., Ulenga, N., Msham, S., Kaishozi, G., Gunaratna, N. S. and Fawzi, W. (2017). Large –scale wheat flour folic acid fortification program increases plasma folate levels among women of reproductive age in urban Tanzania. *Proceedings of the National Academy of Sciences of the United States of America* 12(8): 1-16.

Ogunmoyela, O. A., Adekoyeni, O., Aminu, F. and Umunna, L. O. (2013). A Critical Evaluation of Survey Results of Vitamin A and Fe Levels in the Mandatory Fortified Food Vehicles and Some Selected Processed Foods in Nigeria. *Nigerian Food Journal* 31(2): 52–62.

Osendarp, S. J. M., Martinez, H., Garrett, G. S., Neufeld, L. M., De-Regil, L. M., Vossenaar, M. and Darnton-Hill, I. (2018). Large-Scale Food Fortification and Biofortification in Low- and Middle-Income Countries: A Review of Programs, Trends, Challenges, and Evidence Gaps. *Food and Nutrition Bulletin* 39(2): 315–331.

Peña-Rosas, J. P., Garcia-Casal, M. N., Pachón, H., Mclean, M. S. and 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.

Philar, R., Johnson, Q., Ranum, P., and Wesley, A. S. (2005). Small scale mill fortification manual. Ottawa, Canada: *The Micronutrient Initiative.* (https://www. nutitionintl.org/fr/content/userfiles/sites/2/2017/10/SMALLSCALE MILL. pdf) site visited on 21/05/2020.

Regional Consultative and Capacity Building Workshop on Strengthening Food Fortification Programs (2018). Monitoring and Surveillance Systems. Johannesburg, South Africa, 8-10 October.

Robinson, E. and Nyagaya, M. (2014). Ensuring that food fortification will reach the poor in Tanzania. (https://www.ids.ac.uk/ publications/ ensuring that food fortification will reach the poor in tanzania) site visited on 24/05/2019.

Sarkar, J. Potdar, A. A, and Saidel, G. M. (2018). Whole-body iron transport and metabolism. Mechanistic, multi-scale model to improve treatment of anemia in chronic kidney disease. *PLos Comput Biol* 14(4): 1-34.

Shah, D., Sachdev, H. S., Gera, T., De-Regil., L. M. and 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* (6): 1-102.

Sibhatu, K. T. and Qaim, M. (2017). Rural food security, subsistence agriculture, and seasonality. *Proceedings of the National Academy of Sciences of the United States of America* 12(10). 1-15.

Smith, L., Alderman, H. and Aduayom, D. (2006). Food insecurity in Sub-Saharan Africa: New Estimates from Household Expenditure Surveys. Research Report. International Food Police Research Institute. Washington, D.C. 146: 122pp.

Stoltzfus, R. J., Mullany, L. and Black, R. E. (2004). Iron deficiency anaemia. Comparative quantification of health risks: *global and regional burden of disease attributable to selected major risk factors* (1): 163-209.

Suri, D. J. and Tanumihardjo, S. A. (2016). Effects of Different Processing Methods on the Micronutrient and Phytochemical Contents of Maize*:* From A to Z. *Comprehensive Reviews in Food Science and Food Safety* 15(5): 912–926.

Tanzania Bureau of Standards (2018). Tanzania Standard on Fortified milled maize (corn) products - TZS 328. Tanzania Bureau of Standards, Dar es Salaam, Tanzania, 9pp.

TFNC, (2014) Tanzania National Nutrition Survey. (https://www unicef.org/ esaro/Tanzania National Nutrition Survey 2014. Final report 18012015pdf) site visited on 17/07/2019.

Tulchinsky, T. H. (2010). Micronutrient deficiency conditions: global health issues. *Public health reviews* 32(1): 243-255.

UNICEF, (2012). World Bank, UN Population Division: Levels and Trends in Child Mortality Report—Report 2012: Estimates Developed by the Inter-agency Group for Child Mortality Estimation. New York, USA, 28pp.

UNICEF, (2019). The State of the World's Children. Children, Food and Nutrition: Growing well in a changing world. UNICEF, New York. (https://www.unicef.org/media/60806/file/SOWC) site visited on 10/02/2020.

United Republic of Tanzania (2016). Tanzania National Multisectoral Nutrition Action Plan (NMNAP) for the period July 2016 – June 2021: STRATEGIC PLAN: From Evidence to Policy to action (http://1srw4m 1ahzc2feqoq 2gwbbhk. wpengine.netdna-cdn. com/wp content/uploads/ 2017/03/ BNFB-Annual-Report-2016-FINAL-Annexes-1-and-2) site visited on 23/02/2019.

Van den Wijngaart, A., Bégin, F., Codling, K., Randall, P. and Johnson, Q. W. (2013). Regulatory monitoring systems of fortified salt and wheat flour in selected

ASEAN countries. *Food and Nutrition Bulletin* 34(2 (supplement)): S102-S111.

WHO, (2006). Guidelines on food fortification with micronutrients. Zinc, folate, vitamin B12 and other B vitamins, vitamin C, vitamin D, calcium, selenium and fluoride (edited by Allen, L. et al.). 2006. Geneva, pp. 56-92. (http://www.who.int/iris/handle/10665/43412) site visited on 20/10/2019.

WHO, (2011). Meeting on Regulatory Monitoring of Salt and Flour Fortification Programmes in Asia, 27-29 September 2011, Manila, Philippines. 48pp.

WHO, (2014). Salt reduction and iodine fortification strategies in public health: report of a joint technical meeting convened by the WHO and the George Institute for Global Health in collaboration with the International Council for the Control of Iodine Deficiency Disorders Global Network, Sydney, Australia, March 2013. 36pp.

Williams, J., Mai, C. T., Mulinare, J., Isenburg, J., Flood, T. J., Ethen, M. and Kirby, R. S. (2015). Updated estimates of neural tube defects prevented by mandatory folic acid fortification—United States, 1995–2011. *MMWR. Morbidity and mortality Weekly Report* 64(1): 1-5.

Wilson, R. T. and Lewis, J. (2015). The maize value chain in Tanzania. A report from the Southern Highlands Food Systems Programme, FAO, 53pp.

Wirth, J., Nichols, E., Mas'd, H., Barham, R., Johnson, Q. and Serdula, M. (2013). External Mill Monitoring of Wheat Flour Fortification Programs: An Approach for Program Managers Using Experiences from Jordan. *Nutrients* 5(11): 4741–4759.

World Bank, (2012). Action plan for the provision of vitamins and minerals to the Tanzanian population through the enrichment of staple foods. Washington, DC: World Bank. (Http: //documents.worldbank.org/curated/en/2012/01/ 16408192/action-plan-provision-vitamins-mineralstanzanian-population-

through-enrichment-staple-foods) site visited on 25/10/2019.

CHAPTER THREE

3.0 COMPLIANCE LEVEL AND STABILITY OF MICRONUTRIENTS IN FORTIFIED MAIZE FLOUR TO THE RECOMMENDED TANZANIA STANDARDS

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Abstract

Maize flour fortification was introduced in Tanzania in 2011 in order to address the risk of micronutrients deficiency to children, adolescence and women of child bearing age. Most of millers of fortified maize flour are small scale processors who are exempted from mandatory fortification. They have been doing fortification for more than 3 years and it is important to know whether fortification is carried out as per the recommended standard or not. Therefore, the aim of this study was to assess compliance and stability of fortified processed maize flour with zinc, iron and folic acid by small scale processors compared to the recommended national standards (TZS, 2018). Sixty nine (69) samples of fortified maize flour were collected at point of production and retail outlets in Ubungo in Dar es Salaam and Morogoro Municipality. Micronutrients specifically zinc and iron were analyzed using MP-AES and folic acid was analyzed using HPLC. Micronutrients were significance ($p<0.05$) higher at production area compared to retails. The mean concentrations of iron, zinc and folic acid of production samples were 27.17 ± 1.63 mg/kg, 30.56 ± 2.01 mg/kg and 0.69 ± 0.02 mg/kg, respectively, while at retail outlets samples were 19.34 ± 0.97mg/kg, 21.71 ± 1.50 mg/kg and 0.49 ± 0.02 mg/kg for iron, zinc and folic acid, respectively. Only 31.6% of the assessed samples from production and 12.9% from retail outlets complied with the recommended national standard. The stability of iron, zinc and folic acid for the fortified maize flour stored at room temperature (20 -32^{o}C) for six months was 95.8% for iron, 96.9% for zinc and 66.9% for folic acid. Challenges that hinder processors to attain compliance include; lack of training to create awareness on fortification standards, capacity of processors and access to quality control laboratories. Further investigation on consistency performance of dosifier and consistency training of workers working in the processing unit on the requirements of fortification standard should be done.

Keywords: Fortification, fortified maize flour, micronutrients

3.1 Introduction

Vitamins and minerals are the micronutrients that are required by the body in small quantity and play an important role in the body. The body needs these micronutrients for normal growth and development. Deficiency of these micronutrients in combination with others causes a number of problems including stunting growth in children, reduced cognitive function, anemia, neural tube defect, blindness (Papathakis and Pearson, 2012) and increases the rate of mortality and morbidity especially in children and women of reproductive age (Berti, *et al.*, 2014; Burchi, *et al.*, 2011). To control these deficiencies, food fortification programme was recommended by WHO as the main strategy and the same have been adopted by many countries including Africa (Hoogendoorn *et al.,* 2016).

Micronutrients deficiency in Tanzania is still challenging especially in children and women of reproductive age. According to Tanzania demographic survey report indicated that, 45% of reproductive aged women (15-49) are anemic (TDHS 2015-2016), while 30% had iron deficiency, 35% of children had iron deficiency with high prevalence in children aged 6-11years and 12 – 23 months (NBS and ICF Macro, 2011). Also fifty eight percent (58%) of children aged 6 to 59 months had iron deficiency with anemia. The rate of stunting is 34% and vitamin A deficiency in children aged 0-59 months is 33% while 22% of children are underweight (TDHS 2015-2016; TFNC, 2014). Furthermore in 2013-2018 UNICEF revealed that 29% of Tanzanian children aged 6 -23 months had consumed neither vegetables nor fruits (UNICEF, 2019) which is among the causes of micronutrients deficiency in the body.

The increase in micronutrients deficiencies made the Government of Tanzania to introduce mandatory fortification for vegetable oil, maize and wheat flour in 2011 of which vegetable oil is fortified with vitamin A, wheat and maize flour is fortified with multiple micronutrients zinc, iron, folic acids and vitamin B12. This mandatory fortification was for large scale producers leaving behind small scale processors (Smith *et al.,* 2006).

In Tanzania maize is consumed as major staple food and provide about 50 -80% of the total energy (Kavishe and Harris, 2017). Also there is a large numbers of small scale millers of maize flour around 95% located in urban and village which fed majority of people in the surrounding area (Bymolt and d’Anjou, 2017). Most of consumed fortified maize flour circulated in Tanzanian market is processed by small scale processors who are exempted from mandatory fortification and it is important to know how is accomplished.

However, most of these small scale processors do not have laboratory facilities for performing quality assurance at the mill to ensure the fortified maize flour meet the requirements of the standard (Enzama *et al.* 2017). Also, the compliance of fortified food in LMIC countries Tanzania inclusive were found to be around 40% where by non-compliance food were found labelled as compliant which misled consumers on micronutrients contents of the food (Darnton-Hill *et al.,* 2017). However, there is no reported information regarding compliance of fortified maize flour processed by small scale processors.

Furthermore, the impact of the fortification programme is measured by consistency supply of the desired nutrients at point of consumption (Florence and Tola, 2016). Micronutrients in the fortified food may be accelerated by storage and handling condition of the final product, packing materials and length of storage (Dary and Hurrell, 2006). It is the requirement of the standard that premix and fortificant used during maize flour fortification should have stability such that no more than 20% of its origin activity will be lost when stored for 21 days at 45˚C in well closed container at level of 2.5g/kg in a milled maize product having moisture in the range of 13.5 to 14.5% (TZS, 2018). Therefore, the study assessed compliance and stability of fortified maize flour processed by different small scale processors in Morogoro and Dar es Salaam regions.

3.2 Materials and Methods

3.2.1 Research area

The study was conducted at Ubungo in Dar es Salaam and Morogoro municipality. These two locations were chosen because of high number of processors of fortified maize flour facilitated under SANKU project. Samples were collected at production area from small scale processors who are under fortification programme and were under operation during the research period. Also the fortified maize flour samples from the same processors were collected from retail outlets in the research areas.

3.2.2 Materials

The materials used for this study were aluminum polyethylene bags, polypropylene woven bags and freezer for storing samples.

3.2.3 Study design

Cross sectional design both quantitative and qualitative approach was used in this study where by data were collected at a specific point in time. Collections of data were based on samples collected at production line and retail outlets. Also fresh samples from production were stored at room temperature, the same condition that was used to store maize flour by processors. The stability of micronutrients was studied for a period of six months at interval of three months. Semi structured questionnaires were also used to collect information on challenges faced by small scale processors to attain compliance to the recommended standard.

3.2.3.1 Sampling and sample size

One district from each region (Morogoro municipality in Morogoro region and Ubungo district in Dar es Salaam region) was purposively selected based on the availability of high numbers of processors of fortified maize flour. In Morogoro municipality, six wards were selected using simple random sampling and all processors of fortified maize flour located in these wards were sampled. In Ubungo district three wards were randomly selected and all processors of fortified maize flour located in these wards were sampled (Table 3.1). Large numbers of samples were selected at Morogoro municipality due to availability of high number of processors compared to Ubungo district. Triplicate samples of 1 kg each from the same batch were collected at production area, after which samples were mixed-up to get homogenized composite and about 100 g was kept in air tight aluminum polyethylene bags labelled with unique code number, stored and transported to TBS laboratory for analysis.

Table 3. 1: Fortified maize flour samples collected from production sites in Morogoro Municipality and Ubungo district

S/N	Sampling Site (ward)	Location	Number of samples[a]
1	Kihonda	Morogoro	4
2	Mwembesongo	Morogoro	5
3	Kingolwira	Morogoro	4
4	Uwanja wa Taifa	Morogoro	5
5	Chamwino	Morogoro	5
6	Kingo	Morogoro	4
8	Manzese	Ubungo	9
9	Kimara	Ubungo	1
10	Mbezi	Ubungo	1
	Total		**38**

a. Samples were collected in triplicates from the same batch and composite sample was made to get homogenized sample

Inclusion criteria for sample selection

i. Fortified maize flour processing facility which was in operation during the visit.

ii. The brand of fortified maize flour in the retail outlet from the processing facilities visited

In the retail outlets, a stratified multistage sampling was employed (Kothari, 2004). The first stage, ten wards of Morogoro municipality namely Mwembesongo, Kihonda, Kingolwira, Bigwa, Kiwanja cha ndege, Mazimbu, Mji Mpya, Kingo, Sabasaba and Mafiga were randomly selected from the list of 29 wards. In the second stage, one-sub ward was then purposively selected from each ward based on the volume of trade as advised by ward executive officers. In Ubungo district, 5 wards namely Manzese, Mbezi, Sinza, Kibamba and Kimara were randomly selected from the list of 14 wards. Second one sub ward was purposively selected from each ward based on the volume of trade as advised by ward executive officers. Finally for each small scale processors visited, four samples of the same brand were randomly purchased from different retails shops located in these sub wards. Samples of the same brand were mixed up to get one representative homogenized samples for each processor and a total of 20 brands from Morogoro Municipal and 11 brands from Ubungo Municipal were identified. Therefore 38 brands of fortified maize flour samples were collected from production line and 31 from retail outlets making a total of 69 samples. This sample size was appropriated base on different statisticians who have advised that the sample size of 30 or more is suitable as will provide mean that is very close to the normal distribution (Saunders *et al.,* 2009). Also fresh samples from 8 processors were also collected from production areas, stored at room temperature and the stability of added micronutrients were studied for the period of six months at the interval of three months.

3.2.3.2 Sample handling

About 100 g of the composite sample from each processors and from retail outlet were both kept in air tight aluminum polyethylene bags labelled with unique code number, transported to TBS laboratory. The samples for folic acid analysis were stored in freezer until analysis to prevent loss of vitamins while that for mineral analysis were stored in room temperature. Also fortified maize flour from 8 processors were sampled and kept in in original bags used to pack commercial fortified maize flour (polypropylene woven bags). The samples were stored at room temperature (20 to 32°C) same condition used to store fortified maize flour by processors for the period of January to June 2020 and stability of micronutrients was accessed for six months at the interval of three months. Sample information such as sampling date, brand, manufacturers name, address, sampling source and identification code number were recorded for easy identification of sample.

3.2.4 Equipments

The equipment used for determination of iron, zinc and folic acid were Microwave Plasma-Atomic Emission Spectrometer (MP-AES) Agilent technologies mode 4210 (G8007A version 1.6.0.9255 from Boston -USA, Advanced Microwave digestion system from Sorisole -Italy, five digit weighing balance (Mettler XP205 Toledo from USA), High Performance liquid chromatography (HPLC) (Shimadzu LC-20A, Tokyo-Japan) equipped with autosampler (SIL-10AF), pump (LC 20AT) set at operating pressure of 9.2Mpa, degasser (DGU 20A5), Column oven (CTO-201AC) and photodiode array detector (DAD, SPD-M30A) used for detection of folic acid at wavelength of 284, sterile 50 mL and 15 mL centrifuge tubes from Wertheim – Germany, air dry oven (HERAEUS), centrifuge (Model 300R-Hettich, made in Tuttlingen - Germany), Vortex -Talboys (Troemner LLC, made in New York- U.S.A), Vial 2 mL clear glass and disposable filter 0.45µm pore size from Duren-Germany.

3.2.5 Reagents

The analytical reagents used are nitric acids (NHO_3) 69% AR/ACS LobaChemie PVT LTD from India, hydrogen peroxide (H_20_2) 50% Scharlab S. L of Spain Deionized water prepared using (Evoque water technology, 0.068microliter per second per centimeter), metal standard for zinc and iron (1000mg/L) Agilent technologies from USA, tetra-nbutylammonium hydrogen sulphate ($C_{16}H_{37}NO_4S$), Potassium dihydrogen phosphate (KH_2PO_4) and dibasic sodium phosphate (Na_2HPO_4) both from Loba Chemie Pvt of India, Sodium chloride (NaCl) from Surechem product ltd- England, acetonitrile HPLC grade (sigma aldrich co 3050 spruce street saint louis mo 63103 USA) and folic acid standards of analytical reagent grade batch No. 9.0, 90.7% from France.

3.3 Determination of Iron and Zinc

3.3.1 Sample preparation

Sample analysis for iron and zinc was customized from (Zhao *et al.*, 2015) during which a 0.5 g of fortified maize flour (in triplicates) was weighed using analytical balance and transferred into individual Teflon Microwave Digestion Vessels. Then 5 mL of 32% NHO_3 and 1mL of 30% H_2O_2 were added to the contents in the flask. A blank containing same quantity of reagents without addition of sample was also prepared. The flasks containing samples were transferred into advanced closed microwave system with maximum allowed temperature and pressure of 150^{o}C and 100 bar respectively for digestion. In the digestion chamber, samples were heated up to 150^{o}C from room temperature for 15 minutes. These values were maintained for another 30 min to ensure complete digestion. After digestion, samples were cooled to ambient temperature of about 30^{o}C for another 20 min before handling. The digested samples were transferred into 50 mL Teflon tube, labelled and made up to 50 mL with deionized water read for metal analysis.

3.3.2 Microwave Plasma-Atomic Emission Spectrometer analysis of samples

After digestion, samples were quantified with MP-AES 4210 which used magnetic coupled microwave energy to generate a self-sustained atmospheric pressure using nitrogen plasma. Nitrogen gas was generated from air using nitrogen generator connected to the instrument. The MP-AES was fitted with one nebulizer, double pass spray chamber and the torch. It was also fitted with pump, software that controls the instrument and advanced valve system with four ports (AVS 4) auto sampler. During measurement, samples were typically nebulized prior to interaction with the plasma. The atomized sample passed through the plasma then electrons were promoted to the excited state. The light emitted electron during return to the ground state was separated into a spectrum and intensity of each emission line was measured at the detector.

The detection wavelength of iron and zinc were 371.993 nm and 481.053 nm respectively and these were chosen because they are free from interferences. The speed of pump was set to 15 rpm, sample uptake time was 60 second, rinse time 30 second followed by 15 second torch stabilization. The concentrations of zinc and iron in the sample were calculated according to AOAC 984.27 method as follow:

Actual value (mg/kg) = (Concentration from instrument (mg/L)) ×Total volume (mL)/Sample weight (g)……………………………………………………………….(i)

3.3.3 Quality control

Precision and accuracy of the iron and zinc results were assessed by determining the % recovery and repeatability of analysis of sample spiked with 9 mg/kg. Each measurement was done in triplicates and the % recovery was calculated as per equation (ii).

% Recovery = (Spiked value – Unspiked value) / known spiked concentration)×100… (ii)

Also the initial calibration verification (ICV) immediately after method calibration was done. To monitor stability (repeatability) of the system, Continuing Calibration Verification (CCV) solutions were done after every ten (10) samples to verify if the analysis was within the control limit. A certified reference standards (Agilent technologies) for zinc (10030 ± 30 µg/mL w/v) and iron (10010 ± 40 µg/mL w/v) metals were prepared by diluting the standard with 2% NHO_3 to get stock standard then the stock standard was mixed to get 10 mg/L working standard. This working standard was used to create five point calibration curve (0.1, 0.3, 0.5, 0.7 and 0.9) mg/L for both iron and zinc. Linear calibration curve of intensity versus concentration were constructed and the correlation coefficient (R^2) were also determined as indicated in Figure 3.1

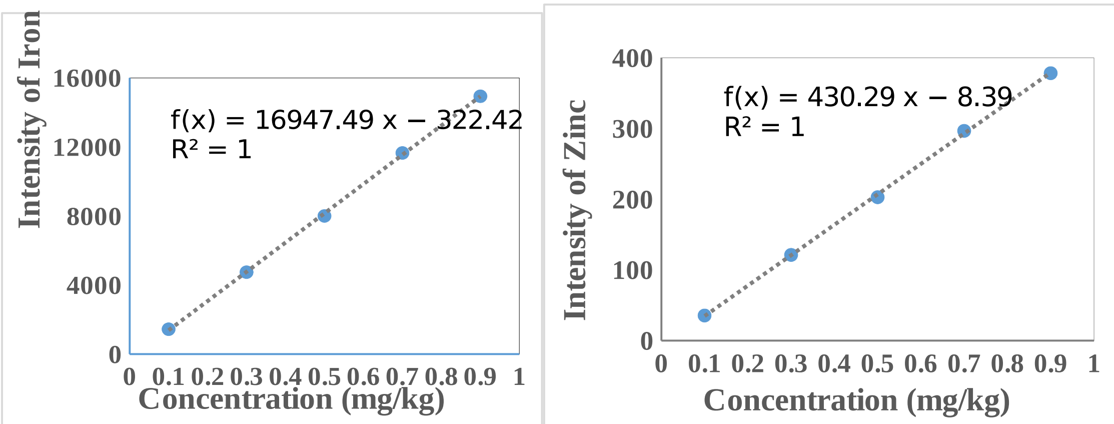


Figure 3. 1: Calibration curves for iron and zinc in fortified maize flour

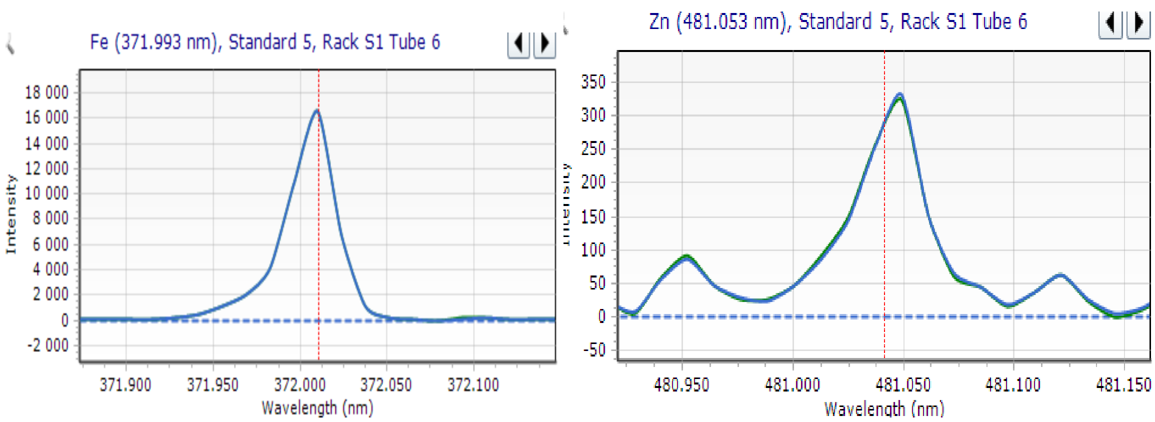


Figure 3.2: Example of MP-AES Chromatogram for iron and zinc standard

3.4 Determination of folic acid

Sample extraction

Analysis of folic acid was done as per Alaburda *et al.*, (2008), and Breithaupt, (2001) methods with slight modifications using HPLC. For each sample 5 g was weighed using analytical balance into empty 50 mL polytetrafluoroethylene centrifuge tubes. Then the tube containing sample was made up to 50 mL using phosphate buffer (0.25M Na_2HPO_4

and 0.37 M KH_2PO_4). The centrifuge tube was vortexed for 10 minutes followed by centrifugation at 4000 rpm for 5 min. After extraction the centrifuged sample was then filtered through 0.45 µm HPLC Chromafil® Xtra MV-45/25 disposable syringe and kept into 2 mL vial for HPLC analysis. All determinations were performed in triplicates.

Preparation of the mobile phases

Mobile phase solution A and B were both prepared using 5 mM tetra-n-butyl ammonium hydrogen sulphate and 25 mM sodium Chloride all from (Loba Chemie Pvt of India) in deionized water. Additionally, mobile phase B containing A and 1 mM dihydrogen potassium phosphate (Surechem product ltd- England) in deionized water and 65% (v/v) acetonitrile (sigma aldrich co 3050 spruce street saint louis mo 63103 USA). Both solutions were sonicated for 10 minutes, degassed for another 10 minutes using Bransonic -wagtech of UK and filtered through 0.45 µm filter paper before introduced to HPLC.

High Performance Liquid Chromatograph (HPLC) condition

Analysis of folic acid was done using HPLC. The stationary phase with HPLC–C_{18} column (5.0 µm particle size, dimensions 150 mm and 4.6 mm, SN E16030645 from German) that enable separation of water-soluble vitamins was used. The column was operated at 30℃. The mobile phase A and B was operated with gradient as shown in Table 3.2. Sample extract was run under flow rate of 1.1 mL/min at injection volume of 20 µL. The chromatogram separation of folic acid was attained at 4.8 min at 284 nm. At 12 min the column was equilibrate in the initial conditions and another sample was initiated. The concentration of folic acid was calculated according to equation (i).

Table 3. 2: Gradient compositions of HPLC during analysis

Time (min)	%A	%B
0	85	15
6	85	15
7	50	50

8	50	50
9	85	15

A is mobile phase consisting of 5Mm tetra-n-butyl ammonium hydrogen sulphate and 25mM sodium Chloride in deionized water. B is a mobile phase containing A and 1mM potassium dihydrogen phosphate in deionized and 65% (v/v) acetonitrile.

3.4.1 Quality control

Quality control was done by spiking the sample with 2 mg/kg of folic acid standard (analytical grade batch No. 9.0 from France- Europe) and the recovery was calculated as per equation (ii). Standard solution of folic acid was prepared by diluting 0.01 g of standard dissolved into 50 mL of buffer solution. The solution was diluted to five different concentration (0.1, 0.3, 0.6, 0.9 and 2) mg/L for generating calibration curve (Fig.3.3) and kept in colored flask for light prevention.

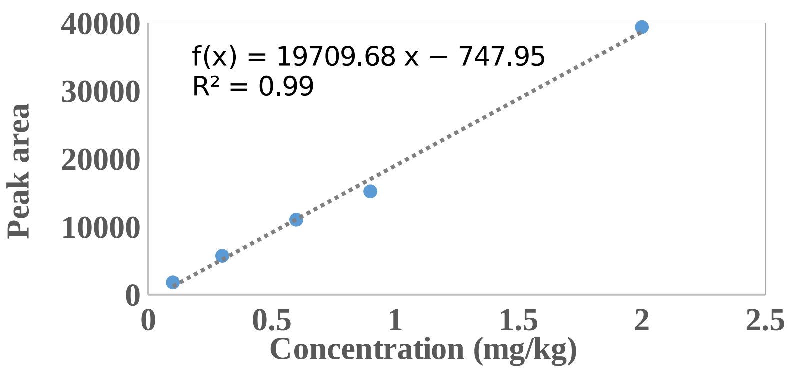
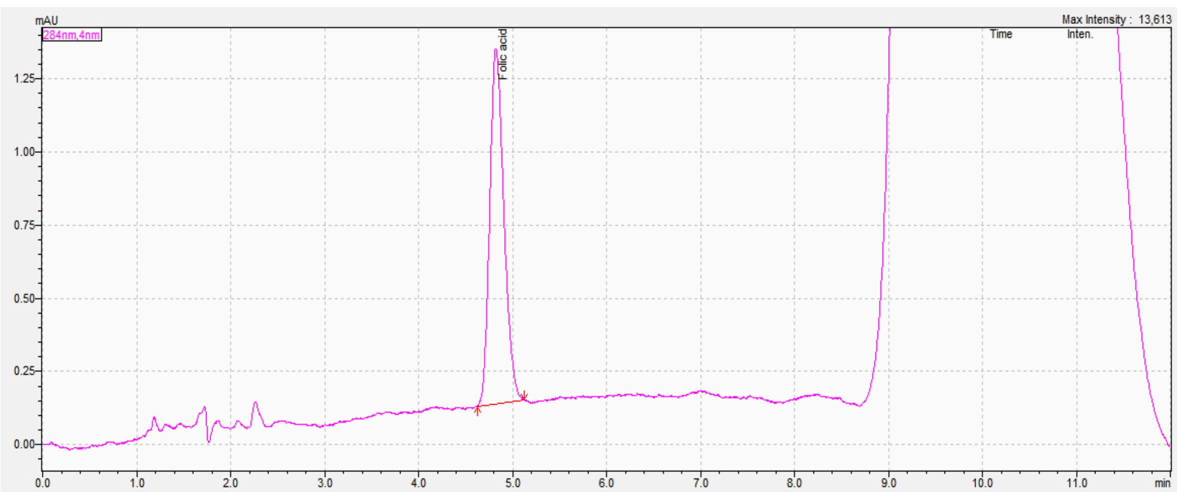


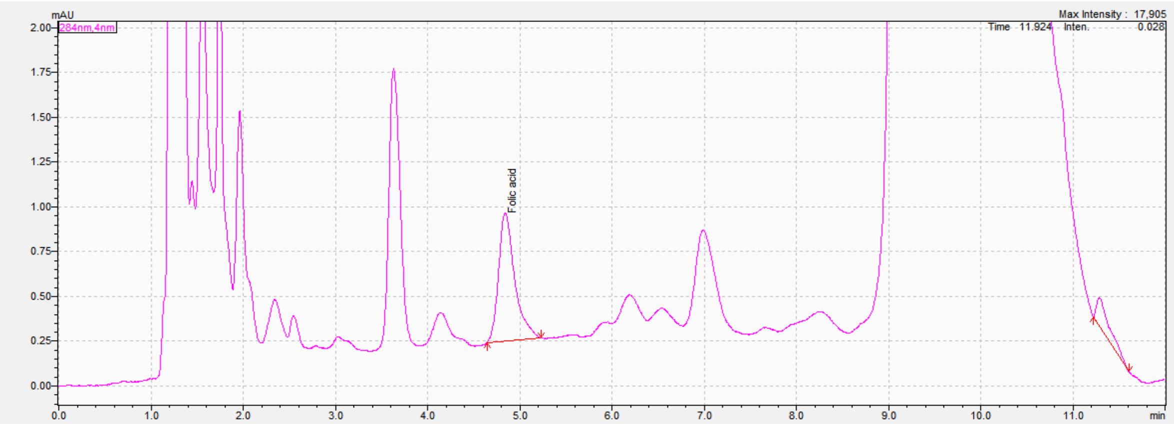
Figure 3.3: Calibration curve for folic acid in fortified maize flour



Retention time (min)

Figure 3. 4: HPLC Chromatogram of folic acid standard

Retention time (T_R) was 4.8 min at concentration of 9 mg/kg. LC 18 column (5.0 µm, 4.6mm ×150mm), mobile phase A consisting of 5mM tetra-n-butyl ammonium hydrogen sulphate and 25mM sodium chloride in deionized water. additionally mobile phase B containing A and 1mM dihydrogen potassium phosphate in deionized water and 65% (v/v) acetonitrile



Retention time (min)

Figure 3.5 HPLC Chromatogram of folic acid present in fortified maize flour sample
Retention time (T_R) was 4.8 min at concentration of 0.95 mg/kg. LC_{18} column (5.0 µm, 4.6 mm ×150 mm), mobile phase A consisting of 5 Mm tetra-n-butyl ammonium hydrogen sulphate and 25 mM sodium chloride in deionized water. additionally mobile phase B containing A and 1mM dihydrogen potassium phosphate in deionized water and 65% (v/v) acetonitrile

3.4.2 Determination of moisture content

Moisture content of fortified maize flour was determined using oven drying method (AOAC, 2000) modified as described by Bradley, (2010). Approximately 10 g of sample was weighed in already dried and cooled aluminum dish and evenly distributed. Then the aluminum dish was placed in an air dry oven (HERAEUS) maintained at 105^{0}C and dried for 3 hours. Then the dishes were covered and placed in desiccator for 30 min to reach the ambient temperature before weighed. The loss in weighted was calculated as moisture content of the fortified maize flour. The calculation was as per equation (iii).

% Moisture Contents = (W2 – W3) / (W2 – W1) × 100……………..………. (iii)

Whereby:

W1=Weight of empty dish (g)

W2 = Weight of empty dish + wet sample (g)

W3= Weight of empty dish + dry sample (g)

3.5 Statistical analysis

Data were analyzed using R software - version 3.5 (2020). Two way Analysis of variance (ANOVA) was used to test significance difference on the level of micronutrients among the production and retail outlet samples as well as storage effects. Means separation was done by Turkey's honest significant difference (HSD) test present in agricolae package in R software. All statistical tests p-value were considered significant at 0.05. Compliance of micronutrients in the fortified maize flour against the recommended national standard was tested using Statistical Package for Social Sciences (IBM SPSS® Version 25, 2017). Frequencies were computed to determine challenges faced by processors in achieving compliance to the recommended standards. A chi-square was computed to assess if there is any association between compliance of fortified maize flour and sample source.

3.6 Results

3.6.1 Recovery of iron, zinc and folic from spiked samples

The accuracy of the method was evaluated by determining percent recovery of iron, zinc and folic acid in spiked flour samples. Recoveries were calculated as per equation (ii) and the obtained results were all above 95% indicating a good recovery and good precision for all replicates (Table 3.3).

Table 3. 3: Recovery of iron, zinc and folic acid from spiked maize flour samples

Micronutrient	Concentration in blank sample (mg/kg)	Concentration in spiked sample (mg/kg)	Spiked concentration (mg/kg)	Recovered concentration (mg/kg)	Recovery (%)[a] n=3
Fe (371.993 [b])	6.35	15.11	9	8.76	99.12±0.30
Zn (481.053 [b])	4.61	13.21	9	8.60	95.57±0.11
Folic acid (284 [b])	0.50	2.49	2	1.99	99.50±0.44

n: values are the means of three different determination ± SE
[a] Recovery= [(spiked sample result - unspiked sample result)/(known spiked concentration)×100]
[b] Wavelength at which the spiked samples were detected.

3.6.2 Level of micronutrients in the fortified maize flour

The mean concentration of the micronutrients analyzed as shown in Table 3.4 indicated that, samples from production sites had mean concentrations which were significant higher than that of retail outlets for all micronutrients tested at $p < 0.05$. The iron for production samples ranged from 5.79 mg/kg to 77.66 mg/kg, zinc from 5.62 mg/kg to 118.15 mg/kg while that of folic acid ranged from 0.29 mg/kg to 1.47 mg/kg. In the retail outlets samples, the concentrations ranged from 6.15 mg/kg to 35.81 mg/kg for iron, 2.67 mg/kg to 46.69 mg/kg for zinc and 0.22 mg/kg to 1.12 mg/kg for folic acid.

Table 3. 4: Average ± SE and range for concentration (mg/kg) of micronutrients in maize flour sample at production and retail outlets

Source of samples	N	Micronutrients concentrations (mg/kg)			Moisture contents
		Iron[1]	Zinc[1]	Folic acid[1]	
Production	38	27.17 ± 1.627^a	30.56 ± 2.013^a	0.69 ± 0.024^a	12.57 ± 0.098^a
Range for production samples		5.79—77.66	5.62—118.15	0.29—1.47	
Retail outlet	31	19.34 ± 0.968^b	21.71 ± 1.498^b	0.49 ± 0.021^b	12.59 ± 0.100^a
Range for outlet samples		6.15—35.81	2.67—46.69	0.22—1.12	

[1] Values are the mean concentration of three replicates times N for each sample and values having different superscript are significantly different at $p < 0.05$. N is number of samples.

3.6.3 Compliance of fortified maize flour with recommended standard

Results on compliance of fortified maize flour to the recommended standard are presented in Table 3.5. According to TZS, (2018) the recommended amount of fortified maize flour was 31±10 mg/kg for iron, 49±16 mg/kg for zinc but the requirements for folic acid was 1.2±0.5 mg/kg at factory and 0.6 mg/kg to 1.7 mg/kg at regulatory level. The results show that more than half of samples from production area (68.4%) did not comply with the recommended standard while at retail outlets point, more than 87.1% did not comply. Analysis of chi square shows that there is no significant association between compliance and source of samples at p>0.05 although the compliance at production tended to be higher than that of retail outlet.

Table 3. 5: Compliance of fortified maize flour as compared to the recommended standard grouped by source of samples

Source of samples	Number of samples	Complied samples	% sample complied	No. of samples not complied	% sample not complied	χ2	P-value
Production	38	12	31.6	26	68.4	3.343	0.07
Retail outlet	31	4	12.9	27	87.1		

The recommended standard value for compliance: iron (31±10 mg/kg), zinc (49±16 mg/kg), folic acid (1.2±0.5 mg/kg). Noncompliance: iron <21 mg/kg>41 mg/kg, zinc <33 mg/kg>65 mg/kg, folic acid <0.6 mg/kg>1.7 mg/kg.

The results from figure 3.6 indicated that, 50% of iron and zinc and 60.5% of folic acid for samples collected at production area complied with the recommended standard while 50% of iron and zinc and 36.8% of folic acid did not complied with recommended standard. On the other hand, 51.6% of iron, 38.7% of zinc and 25.8% of folic acid for the retail outlet samples complied with the recommended standard while 48.4% of iron, 61.3% of zinc and 74.2% of folic acid did not comply with the recommended standard.

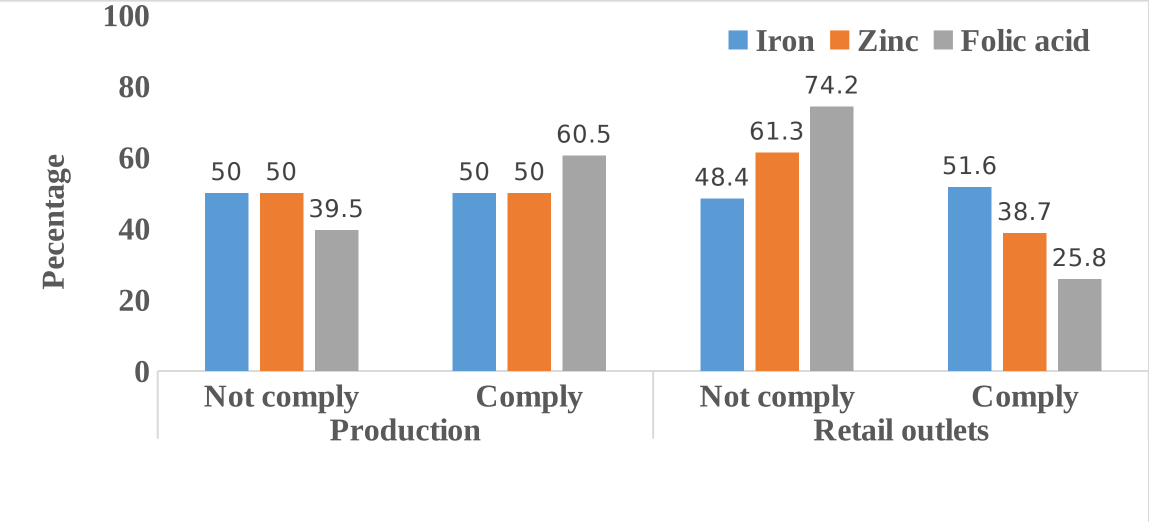


Figure 3.6: Compliance of specific micronutrient with the recommended standard
Compliance: iron (31±10 mg/kg), zinc (49±16 mg/kg), folic acid (1.2±0.5 mg/kg). Noncompliance: iron <21 mg/kg>41 mg/kg, zinc <33 mg/kg>65 mg/kg, folic acid <0.6 mg/kg>1.7 mg/kg.

More analysis was done to compare the compliance of specific micronutrients at production and those from retail outlets. A chi square results indicated that no statistical significance between compliance of iron at production and those of retail outlets ($\chi2$ = 0.018, p=0.8). Although they did not show significance difference, iron at retail outlets tends to be higher than those of production. Also five (5) samples (13.2%) from production were above the recommended standard while 14 samples (36.8%) were below the recommended standard. In the retail outlets 48.4% of the samples were below the recommended level and none of them exceeded the recommended level (Fig.3.7).

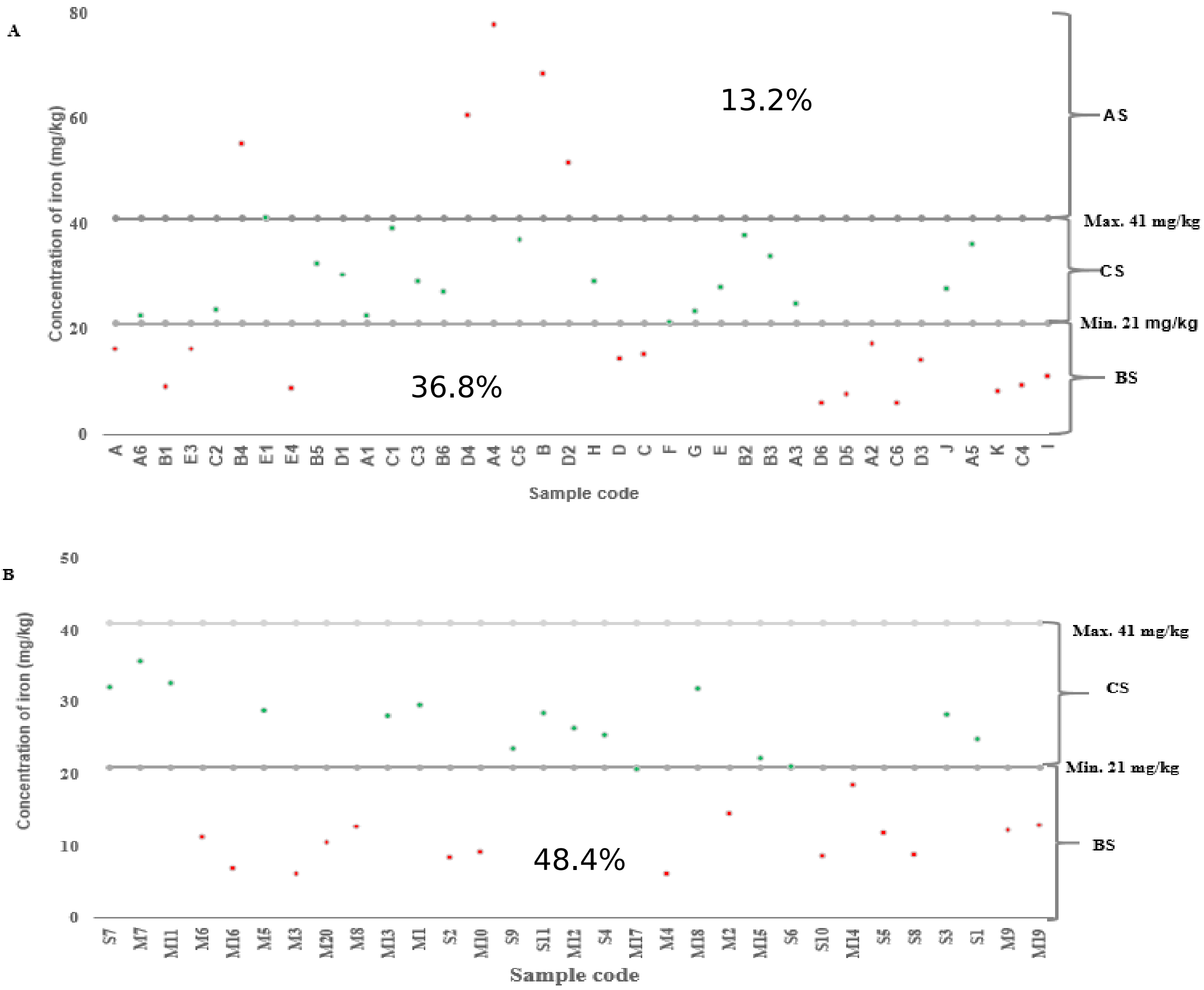


Figure 3.7: Mean distribution of iron concentration for the composite samples of fortified maize flour

Iron content of fortified maize flour for production samples (A). iron contents of fortified maize flour samples from retail outlets (B). all samples were measured in triplicates. samples that lies above recommended level (AS). sample that lies below the recommended level (BS). compliance samples to the recommended standard (CS).

The analysis of zinc indicated high compliance in production compared to that of retail outlet but the level was not significant at p=0.34. About half of production samples (47.4%) were below the recommended level and 2.6% exceeded the recommended level while 61.3% of the retail outlets samples were below the recommended level (Fig.3.8)

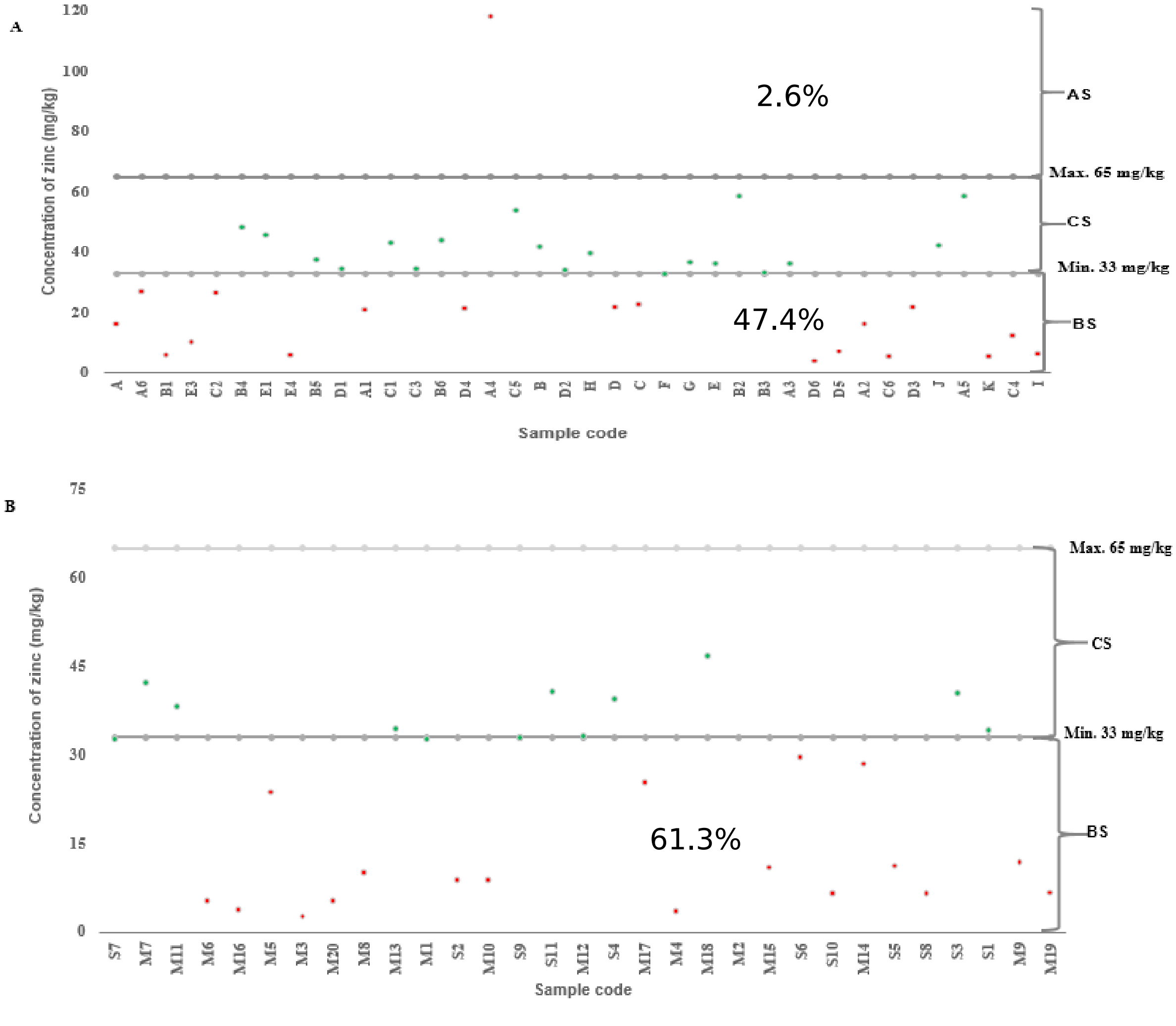


Figure 3.8: Mean distribution of zinc concentration for the composite samples of fortified maize flour

Zinc content of fortified maize flour samples from production (A). zinc contents of fortified maize flour samples from retail outlets (B). all samples were measured in triplicates. samples that lies above recommended level (AS). sample that lies below the recommended level (BS). compliance samples to the recommended standard (CS).

Furthermore, the analysis of folic acid in fortified maize flour for the samples collected indicated that the compliance of folic acid at retail outlet was significantly lower than that of production at p=0.0002. Also more than one third (39.5%) of production and 74.2% of retail outlets samples were below the recommended standards (Fig.3.9)

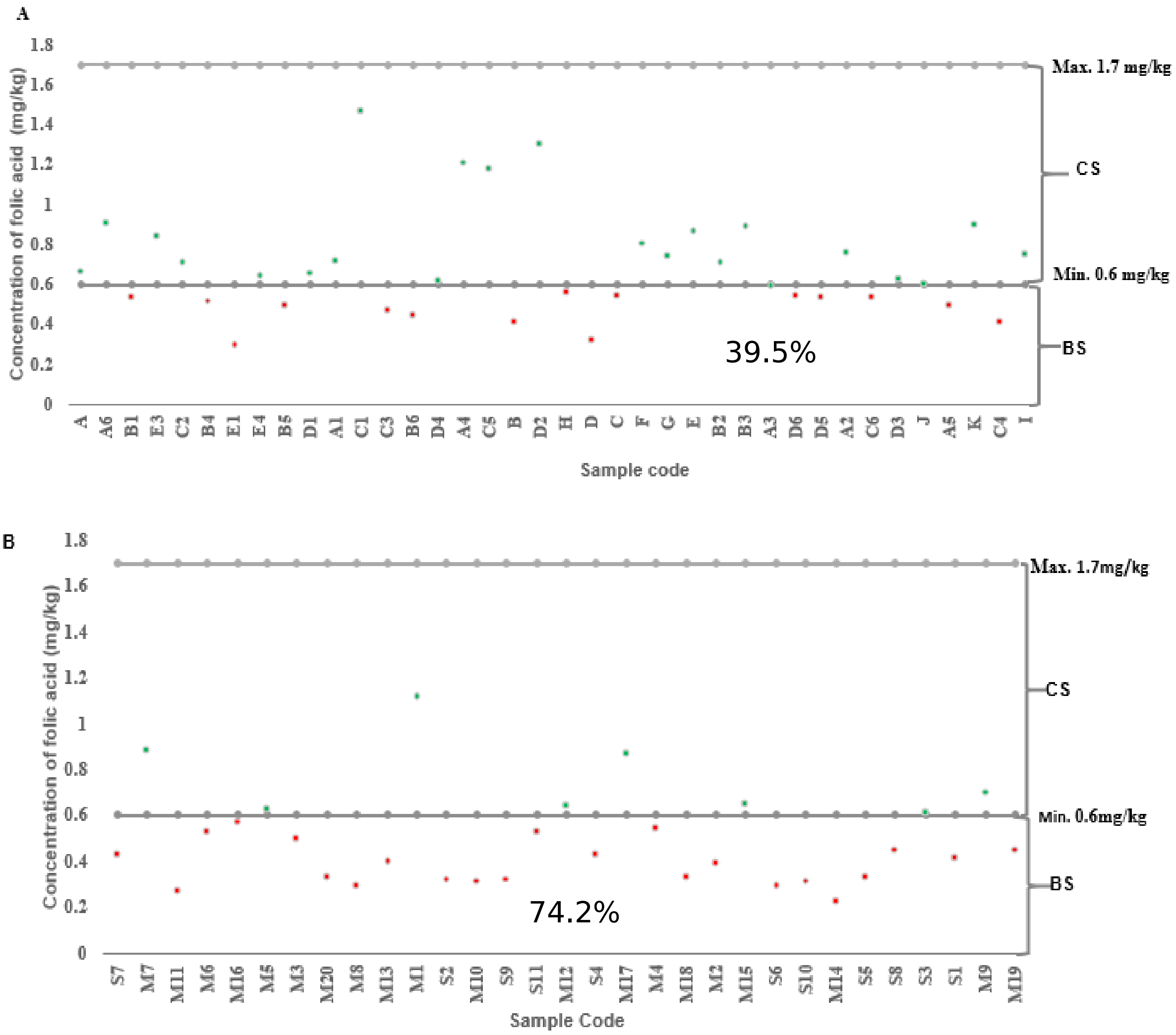


Figure 3.9: Mean distribution of folic acid concentration for the composite samples of fortified maize flour

Folic acid content of fortified maize flour samples from production **(**A). folic acid contents of fortified maize flour samples from retail outlets (B). all samples were measured in triplicates. sample that lies below the recommended standard (BS). compliance samples to the recommended standard (CS).

3.7 Challenges faced by manufacturers in ensuring the fortified maize flour comply with the recommended standard

3.7.1 Demographic details

To explore challenges faced by manufacturer to attaining compliance to the recommended national standards, interviews were conducted with personnel involving in fortification at factory level. During survey a total of 38 small scale processors were interviewed, 50% of the respondents were company directors, 10.5% company managers. Other respondents were company supervisors (26.3%) and millers (13.2 %) (Fig.3.10). More than one third

(39.47%) of the respondents had completed primary education, 31.58% completed ordinary education, 18.42% completed advanced education and 10.53 completed higher education level. The majority of the respondent (92.10%) were males and only (7.9%) were females of which (57.9%) among them aged between 31 to 45 years while 13.16% aged between 46 to 55, 10.53% aged between 18 to 30 and 18.4% of the respondents were over 56 years old.

Figure 3.10: Proportion of respondents interviewed from factory

Different challenges faced by small scale processors of fortified maize flour to attain compliance to the recommended standard were explored from processors. The interviewed processors explored training and fortification awareness, as the main challenges followed by laboratory capacity, workers skills and technical capability (Fig.3.11)

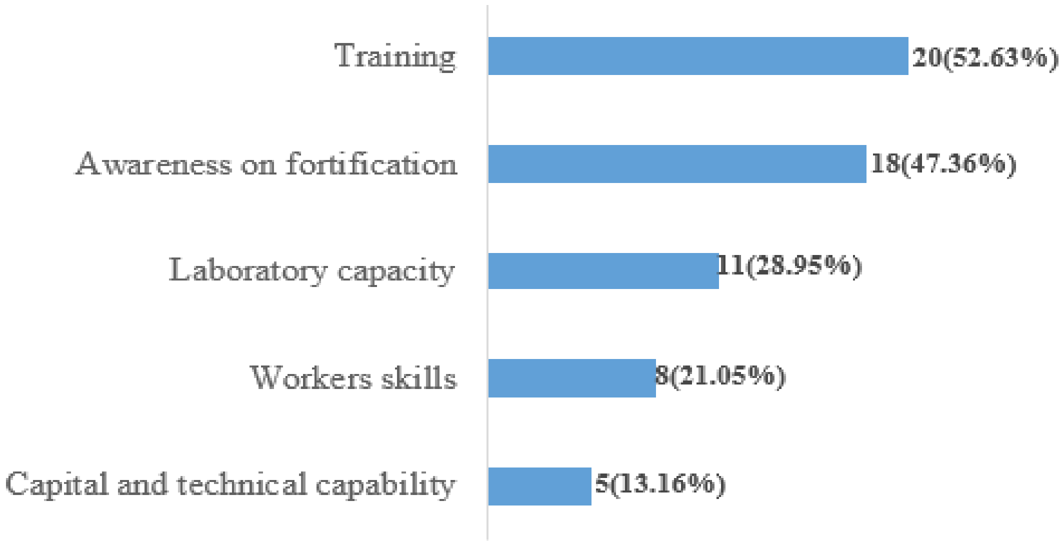


Figure 3.11: Challenges faced by processors of fortified maize flour in ensuring fortification compliance (N=38), the values are the numbers and percentage of respondents

3.7.1.1 Training

Training is one of the tool that enable personnel to perform better in the specified field. Majority of respondent (52.6%) reported that, lack of consistence training in the mills especially in the area of quality assurance and fortification standards as major challenges to ensure fortified flour meet the recommended standard. During the study, it was observed that, 39.5% (15) of the processors were not aware about national maize flour fortification standards, while 15.79% (6) were not conversant with the recommended standards. It was also observed that employees in the company were not permanent which makes most of them missing the training offered by the governmental institutions.

3.7.1.2 Awareness and consumers attitudes on fortification

Majority of respondents (47.36%) reported awareness and attitudes of consumers towards food fortification as major challenges in attaining the compliance to the recommended standards. The study observed that, more than half of the respondents 27 (71.05%) were aware with fortification practices and the rest 11 (28.95%) did not know why they are doing fortification.

Most of the respondents recommended that awareness on fortification should be ongoing process because not all of people know the importance of consuming fortified food. Majority of processors are not in fortification program because most of consumers preferred unfortified maize flour due to lack of knowledge on the benefits of consuming fortified maize flour. Two of the respondent recommended that; voluntary fortification will not produce the desired effect. That, the government needs to review fortification programme or introduce by laws which will govern all processors of fortified maize flour to operate under the same conditions. Also some of processors suggested that, the importance of consuming fortified food should be promoted to majority of people from low level including children in schools through radio, televisions programme and brochures.

3.7.1.3 Laboratory capacity

Most of processors (28.95%) reported that, laboratory was one of challenge in ensuring fortified maize flour processed meet the recommended standard. Few processors (13.2%) analyze their fortified maize flour using external laboratory and only one (2.6%) had instruments for qualitative iron test. It is also the responsibility of the government to undertake external quality control of the product to make sure the processed flour are adequately fortified as reported by 71.05 % of processors.

3.7.1.4 Workers skills, capital and technical capability

Most of processors (21.05%) reported workers skills and 13.15% reported technical capability as one of the challenges in ensuring the fortified maize flour complied with the recommended standards. Four (04) of the respondent recommended that; having skills and technical capability especially on dosifier is very important as will help processors during technical faulty of machine instead of waiting for technician from supplier. They also said that for sustainability of fortification, it is important for the processors to own the programme. Facilitation of fortification programme to small scale processors is project driven and they also rely on donor for supplying dosifier and premix including the technical capability on operation and management of equipment. This raise questions on sustainability of the programme.

3.8 Stability of micronutrients of fortified maize flour stored under room temperature

Table 3.6 shows the effect of storage time on the level of micronutrients in fortified maize flour. Both micronutrients were within the limit of the recommended standard in all six months of storage. The statistical analysis indicated that, storage time had no effect of the level of zinc content for all six months of storage. It also implied that, no significant change of iron for the first three months of storage but the significance decrease at $p < 0.05$ was observed at the end of six month. Folic acid decreased significantly to all six months of storage. Moreover, the significant increase in moisture was observed in all months of storage.

Table 3. 6: Mean of micronutrients in fortified maize flour stored at room temperature

Storage time	Micronutrients content (mg/kg)			% Moisture contents[1]
	Iron[1]	Zinc[1]	Folic acid[1]	
Month 0	31.07±1.311[a]	39.09±2.331[a]	0.89±0.059[a]	12.87±0.102[a]
month 3	30.65±1.306[a]	38.27±2.380[a]	0.70±0.040[b]	13.50±0.067[b]
month 6	29.74±1.346[b]	37.87±2.378[a]	0.60±0.040[c]	13.78±0.055[c]

The superscript values followed by the same letter in the column are not significant at $p > 0.05$
[1]data are the results of mean and SE of eight samples stored at room temperature (20°C -32°C) measured in triplicates

3.9 Discussions

3.9.1 Level of micronutrients in the fortified maize flour

Although all processing facilities visited use the same technology in fortifying maize flour as well as same the premix supplied by one supplier, the level of micronutrients obtained in the samples collected varied between one processor to another. The obtained mean concentrations of micronutrients in fortified maize flour appeared to be statistically different at $p<0.05$ among production and retail outlets samples as shown in Table 3.4. This could be due to inadequate mixing of the maize flour during fortification. The study in Cameroon reported different and low level of micronutrients in fortified wheat flour for the market samples compared to the industry samples and concluded that, inadequate mixing of product during fortification as the major cause (Mark *at al.*, 2019). Also lack of internal monitoring of fortified maize flour can be the cause of inconsistency level of micronutrients observed in the current study as observed during survey that only 2.6% of processors had capacity of conducting qualitative analysis of the fortified maize flour at the factory. The findings observed in the current study was similar to post market surveillance conducted by the former TFDA on wheat flour which revealed inadequate quality control at the factory as factor that contributes to inconsistency micronutrients (Noor *et al.*, 2017). Also, Enzama *et al*. (2017) reported that quality control facilities was problem in most African countries and fortification was not owned by the small mills as they consider undertaking quality control at the mill as the additional costs which was also contributed by lack of knowledge on quality control and quality assurance.

3.9.2 Compliance of fortified maize flour with the recommended standard

Despite of the initiatives taken by the Government to control diseases related to micronutrients deficiencies, compliance of fortified maize flour to the recommended Tanzanian standard is still a challenge. This was justified by noncompliance of 76.8% for the total samples collected from production and retail outlets. This findings was higher than the one reported in Nigeria whereby only 45% of maize and wheat flour, sugar and vegetable oil for the samples collected from the factory complied with the recommended Nigerian standard (Ogunmoyela *et al.,* 2013).

The observed low level of compliance in fortified maize flour in the current study could be attributed by operation of small scale processors of fortified maize flour in Tanzania under voluntary basis of which they are not bounded by the laws and regulations in making sure the final products are adequately fortified. Food fortification programme was desired to control micronutrients deficiency through delivery of quality and safe food to the targeted group of people. Consumers bought products relying on manufacturers claims on labelling regarding nutritional quality information and they can be misled (Mkambula *et al.,* 2020) by manufacturer when operation is under voluntary and food control agencies have not been powered to enforce the standard (Hoogendoorn *et al.,* 2016). Voluntary fortification was introduced in Tanzania to small scale processors in order to increase the coverage of fortified food since most of maize flour is produced by small scale processors. Zimmerman *et al.,* (2014) found that, the coverage of iodized salts increases from 40% to 49% to countries which operated under voluntary fortification compared to 49% to 72% for countries which operated under mandatory fortification. Voluntary fortification of maize flour could weaken the fortification programme if not well monitored leaving targeted people consuming non fortified, under/over fortified food (Mkambula *et al.,* 2020) due to challenges associated with consistency fortification of the product with adequate amount of micronutrients (Berry *et al.,* 2010).

a) Iron

The current study was able to analyze specific micronutrients in fortified maize flour for the samples collected from production and retail outlets. The obtained compliance of 50% from production samples and 51.6% of retail outlets samples was higher than those reported in Nigeria for the fortified maize flour from factories and markets where the compliance level was only 18.2% and 81.8% did not complied with the recommended Nigerian standards (Ogunmoyela *et al.*, 2013). Moreover, the obtained level of compliance as shown in (fig. 3.9) could be due to lack of internal monitoring of the product during fortification and insufficient addition of micronutrients at factory level. Similarly the study conducted in South Africa reported the insufficient addition of micronutrients at the factory as the major causes of low level of compliance in fortified flour (Yusufali *et al*., 2012). Uncontrolled fortification practices at factory can also lead to excessive or inadequate level micronutrients in the finished products which put in danger the health of consumers if the dose rich toxic level or the amount of consumed nutrients is ineffective (Traore, 2008).

b) Zinc

The aim of fortification is to ensure the right and correct amount of micronutrients reach the targeted group of people to prevent certain heath condition without exceeding or lowering the recommended level of micronutrients (Dwyer *et al.*, 2014). The level of zinc reported in Fig.3.8 was higher than the one reported in Kenya whereby, only 22.2% of zinc in fortified maize flour was below the recommended Kenyan standard (Khamila *et al.*, 2020). The observed variation of the results could be attributed by inconsistency dozing and mixing of micronutrients by dosifier during fortification. The study by Yusufali *et al.*, (2012) in South Africa concluded that the insufficiency addition of micronutrients at factory level causes a great variation of micronutrients in fortified food.

c) Folic acid

The fortified maize flour analyzed had folic acid level ranging from below the recommended level 0.22 mg/kg to maximum of 1.47 mg/kg. The compliance of samples from retail outlets (25.8%) was almost the same as the one reported in Kenya (29.6%) in the fortified maize flour collected from the market. Also the obtained low level of compliance in the current study as shown in (Fig 3.9) was higher than the one reported by Khamila *et al.,* (2020) in fortified maize flour whereby only 11.1% were below the detectable limit. The higher level of below fortification in the samples could be attributed by inadequate mixing of product during fortification and improper handling and storage of the product in the market. During survey, the fortified maize flour was found exposed direct to sunlight and others were kept open in air which resulted in loss of vitamin. This was supported by the study conducted in Brazil on fortified corn and wheat flour which reported that inadequate homogenization of vitamin at processing stage causes a low level of micronutrients (Boen *et al.,* 2008). Moreover, vitamins are susceptible to deterioration when exposed to unfavorable environment such as light, temperature, relative humidity and oxygen (Dunn *et al.,* 2014; Kuong *et al.,* 2016). It was recommended by Luthringer *et al.,* (2015) that poor storage conditions results in reduction of retention capacity of vitamin which can lead to non-compliance of the fortified product.

3.10 Challenge faced by processors to attain compliance to the recommended standard

The study identified five major challenges faced by small scale processors in archiving compliance to the recommended standard (TZS, 2018). The leading challenges were Training, awareness and attitudes of consumers on food fortification, followed by laboratory capacity, workers skills, capital and technical capability.

3.10.1 Training

The sustainability of fortification programme is effective when effective training is implemented as it helps workers to own the programme and increases conformity to standard. The reported main challenges faced most of processors (52.6%) in the area of training on fortification standard (39.5%), maintenance and calibration of dosifier was in line with the study conducted in Morocco whereby, insufficient training of the factory workers were identified as the main challenges to attain compliance of fortified food (Berger, 2009). Also, it was reported by Luthringer *et al.*, (2015) that most processors lack trained staff with technical capability which hinders the fortification practices. Training gaps in all aspects of fortification including fortification standards, premix handling and storage, calibration and maintenance, and quality assurance practices can easily be addressed with a skilled workforce (WHO, 2016). For proper implementation of fortification programme training should be done to all workers at the factory regardless of their positions.

3.10.2 Awareness and attitudes on fortification

It is important for both processors and consumers to be aware of the existence and importance of fortified food in order to increase the coverage of consumption of fortified food. Low level of awareness and consumers attitudes on food fortification (47.36%) as reported in the current study was in line with the study conducted in South Africa whereby lack of awareness on fortification among millers and poor communication among various stakeholders were identified as factors which contributed to decline of fortification programme and caused 45.3% of children aged 1-9 years to suffer from zinc deficiency (Sunley and Umunna, 2010). Awareness on fortification should be ongoing process because not all of people know the importance of consuming fortified food. Tanzania is surrounded by a number of small scale processors who are not in the fortification programme due to lack of knowledge on the benefits of consuming fortified maize flour. The promotion on the importance of processing and consuming fortified food from low to high level through radio and televisions programme as recommended by six (6) processors could produce the desired effect. This was supported by the social market campaign developed by Ministry of Health and UNICEF in 2008 aiming at raising awareness on fortification logo through television, radio and promotion materials which resulted in 61% of consumers and more than 50% of distributors to recognize fortification logo (Wirth *et al.*, 2013; Berger, 2009). Also the advertisement through radio and community activation in Kenya and Tanzania impacted knowledge regarding food fortification to more than 1600 reproductive aged women (Martin *et al.*, 2016). Marketing of fortification programme through radio contributed in raising awareness of fortified food. Impacting proper knowledge to all workers working in the mills will be the best approach since they will be ambassador to other people sourcing service from them who have never been trained or heard on food fortification.

3.10.3 Workers skills, capital and technical capability

Facilitation of fortification programme to small scale processors is project driven (ECSA, 2017) and they also rely on donors for supplying dosifier and premix including the technical capability on operation and management of equipment. This raise question on sustainability of the programme as reported by 21.05% out of 38 processors that lack of workers skills including technical capability as main challenges they face to attain compliance. Knowledge and skills of workers in different aspects of fortification is required for proper implementation of fortification programme. Poor knowledge and skills on fortification have been reported as the main causes of 10% of the mills who were found using fortification logo but were not fortifying their products (Khamila *et al.*, 2019). Having skilled and trained workers in fortification programme especially in the area of operation, calibration and maintenance of dosifier including quality assurance, handing and storage of premixes increases the level of compliance (WHO, 2016). As the fortification was donor dependent, impacting technical knowledge and skills to processors could reduce the amount of unfortified maize flour with fortification logo in the market. This is because the study revealed that processors did not have knowledge on maintenance of dosifier when technical fault occurs and they usually inform the supplier of dosifier for rectification. At this waiting period processors proceed with maize flour processing and packed in already printed bags with fortification logo. This causes circulation of unfortified product in the market having fortification logo. It has been reported by Berger (2009) that the main challenge faced by processors to comply with fortification is lack of skills and capacity on feeder installation.

3.10.4 Laboratory capacity

The effective implementation of fortification programme require internal monitoring of the fortified food to make sure that, the food contains adequate micronutrients before consumption. In the current study processors (85.5%) lack laboratory instruments for flour analysis to confirm its quality which was in line with the study reported by Luthringer *et al.,* (2015) which revealed that lack of laboratory instruments as the main challenges that hinder compliance. This made the fortified maize flour processed by small scale processors to be dispatched to the market with unknown quality.

3.11 Stability of iron, zinc and folic acid in the fortified maize flour stored at room temperature

The efficacy of fortification is measured by ensuring the fortified food reaches the targeted group of people with the desired level of micronutrients (Florence and Tola, 2016). This depends on the stability of micronutrients added in food at various conditions.

The analysis from this study indicated that stability of iron and zinc in fortified maize flour stored at room temperature for six months was more than 95% with only 4.2% and 3.2% loss in iron and zinc respectively (Table 3.7). Statistically there was a significant change of iron at the end of six month which might be due to solubility of NaFeEDTA in water (Hurrell, 2021) as during storage, moisture contents was observed to increase significantly for all six months of storage. Stability of minerals in fortified flour stored at room temperature is supported by the study conducted by Rosado (2005) whereby more than 95% of iron was retained in corn flour stored for 90 days with no significant change in zinc content. Also in 2004, Nuzhat reported 97-100% of iron stability in wheat flour. Moreover high stability of more than 90% of iron contents was also reported by Kuong *et al.* (2016) in the fortified cold extruded rice stored for 12 months. The observed results could be attributed by the stability of minerals added in fortified maize flour. Another study demonstrated that, minerals are very stable than vitamin on exposure of different conditions such as light, heat and temperature (Miller, 2008). Also lack of iron in form of ionic form in NaFeEDTA makes it to be more stable and prevent easy dissociations of iron from EDTA (Sharma *et al.*, 2020). The observed % loss of iron 1.3% and zinc 2.1% in the present study at the end three months were less than 14% loss in iron reported by Rosado (2005) in fortified pasta stored at room temperature for two months and 4.39% loss in zinc reported by Akhtar *et al.* (2010) in chapattis made by fortified wheat flour stored for two months at room temperature.

Table 3. 7: Stability of micronutrients in fortified maize flour

Micronutrients	Stability in 3 month (%)	Stability in 6 month (%)	Loss in 3month (%)	Loss in 6 month (%)
Iron	98.7	95.8	1.3	4.2
Zinc	97.9	96.9	2.1	3.2
Folic acid	78.3	66.9	21.7	33

Stability of micronutrients (%) in fortified maize flour during 6 month for the samples stored at room temperature. loss (%) = ((initial concentration of micronutrient -final concentration of micronutrient)/ initial concentration of micronutrient) x 100, stability (%) = (final concentration of micronutrient/initial concentration) x 100

Stability of folic acid added in fortified maize flour was higher in the first three months 78.3%, and decreased to 66% at the end of six month. The percentage loss of folic acid was 21.7% at the end of three months and increased significantly to 33% at the end of six month. The decrease in stability of folic acid in the fortified maize flour could be influenced by the significant increase in moisture contents as observed in all six months of storage (Table 3.6). This was supported by the study conducted in Brazil which observed a significance decrease in folic acid for the corn flour samples which were stored at room temperature and had remained with expiry date of one, three and five month respectively (Boen *et al.,* 2008). High losses of folic acid in the first three month for the fortified flour samples stored in paper bags at 25 - 40^{o}C has been also reported by Hemery *at al.* (2020) ranging from 21 - 49%. Losses of folic acid observed in the current study could be associated by the instability of folic acid in high temperature, light and moisture. Folic acid is water soluble vitamin and high moisture contents accelerate its solubility. Dunn *et al.* (2014) has reported that, both packaging materials, moisture contents, and duration storage time has affected micronutrients in fortified food.

3.12 Conclusions

The study indicated low level of compliance for the fortified maize flour to the recommended national standard for both production and retail outlet samples. The most probable reasons for the observed noncompliance are the inconsistency and under addition of micronutrients at factory level due to lack of technical knowhow, lack of internal monitoring of final product at the factory during processing which make the product to be released to the market with unknown quality. Also, improper storage of premix and fortified maize flour could be the cause of low compliance especial in folic acid since they are highly affected by sunlight and excessive heat. Lack of consistency training to processor regarding fortification standard and it's important together with workers skills cause low compliance of fortified product. Finally the operation of small scale processors under voluntary basis contributes to low level of compliance since the processors are not abide with laws and regulations to make sure the product are adequately fortified. Furthermore, the stability of micronutrients in fortified maize flour packed in polypropylene bags and stored at room temperature for six months was more than 95% for minerals and 66% for folic acid.

3.13 Recommendations

For proper implementation of fortification programme and to ensure the recommended amount of micronutrients reach the targeted people, it is recommend that investigation on performance of dosifier to be conducted to analyze the feeding rate in order to remove the inconsistency and under addition of micronutrients at production. Also the government should extend training on fortification on the required standards to all employees working in the factory regardless of their positions. While waiting for the small scale processors to have capability of analyzing the product at the factory, the government to enhance the frequency of monitoring the fortified products to confirm its compliance. Finally the government should introduce by laws which will govern all small scale processors of maize flour to fortify their product in order to introduce equal level in the playing field and hold noncompliant processors accountable.

REFERENCES

Akhtar, S., Anjum, F. M., Rehman, S. U. and Sheikh, M. A. (2010). Effect of storage and baking on mineral contents of fortified whole wheat flour. *Journal of Food Processing and Preservation* 34: 335–349.

Alaburda, J., de Almeida, A. P., Shundo, L., Ruvieri, V. and Sabino, M. (2008). Determination of folic acid in fortified wheat flours. *Journal of Food Composition and Analysis* 21(4): 336-342.

Berger, J. (2009). National fortification of wheat flour and oil with micronutrients in Morocco: 2005–2008 project supported by GAIN. Geneva: *Global* Alliance for Improved Nutrition.

Berry, R. J., Bailey, L., Mulinare, J., Bower, C. and Dary, O. (2010). Fortification of flour with folic acid. *Food and nutrition bulletin* 31 (1-suppl1): S22-S35.

Berti, C., Faber, M., and Smuts, C. M. (2014). Prevention and control of micronutrient deficiencies in developing countries: current perspectives. *Nutrition and Dietary Supplements* 6: 41-57.

Boen, T. R., Soeiro, B. T., Pereira-Filho, E. R. and Lima-Pallone, J. A. (2008). Folic acid and iron evaluation in Brazilian enriched corn and wheat flours. *Journal of the Brazilian Chemical Society* 19(1): 53-59.

Bradley, R. L. (2010). Moisture and total solids analysis. In: Food analysis. (Edited by Nielsen, S. S) Springer, Madison, USA. 85-104 pp.

Breithaupt, D. E. (2001). Determination of folic acid by ion-pair RP-HPLC in vitamin-fortified fruit juices after solid-phase extraction. *Food Chemistry* 74(4): 521–525.

Burchi, F., Fanzo, J. and Frison, E. (2011). The Role of Food and Nutrition System Approaches in Tackling Hidden Hunger. *International Journal of Environmental Research and Public Health* 8(2): 358–373.

Bymolt, R. and d'Anjou, J. (2017). Lessons on small and medium-scale maize flour fortification in Tanzania: Lessons learned from the Millers Pride – Lishe Bora project. (https://www.wvi.org/sites/default/files/Millers%20Pride%20DSM%20Tanzania.pdf) site visited on 20/10/2018.

Darnton-Hill, I., Neufeld, L., Vossenaar, M., Osendarp, S. and Martinez, H. (2017). Large scale food fortification: an overview of trends and challenges in low- and middle-income countries. (https://micronutrient forum.org/content/userfiles /2017/01/2017-01-25 MNForum FortificationReport-Updated.pdf) site visited on 16/07/2019.

Dary, O. and Hurrell, R. (2006). Guidelines on food fortification with micronutrients. World Health Organization, Food and Agricultural Organization of the United Nations: Geneva, Switzerland. (http://www.fao.org/3/X5244e04.htm) site visited on 12/03/2020.

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

Dwyer, J. T., Woteki, C., Bailey, R., Britten, P., Carriquiry, A., Gaine, P. C. and Smith Edge, M. (2014). Fortification: new findings and implications. *Nutrition reviews* 72(2): 127-141.

ECSA, (2007). Manual for internal monitoring of fortified maize flour first edition (https:// ecsahc.org/wp-content/uploads/2017/06/Manual-for-Internal monitoring-of-Fortified-Maize-Flour.pdf) site visited on 12/04/2020.

Enzama, W., Afidra, R., Johnson, Q. and Verster, A. (2017). Africa maize fortification strategy 2017–2026. Online: Smarter Futures. (https://www.tfnc.go.tz/uploads/ publications/sw1515868626-Africa %20Maize %20Fortification%20Strategy %202017-2026.pdf) site visited on 26/03/2020.

Florence, N. U. and Tola, A. (2016). Vitamin A stability in Nigerian wheat flour and fortification compliance level. *African Journal of Food Science* 10(3): 33–40.

Hemery, Y. M., Laillou, A., Fontan, L., Jallier, V., Moench-Pfanner, R., Berger, J. and Avallone, S. (2018). Storage conditions and packaging greatly affects the stability of fortified wheat flour: Influence on vitamin A, iron, zinc, and oxidation. *Food Chemistry* 240: 43-50.

Hoogendoorn, A., Luthringer, C., Parvanta, I. and Garrett, G. (2016). Food Fortification Global Mapping Study. Technical Assistance for Strengthening Capacities in Food Fortification. European Commission. (https://ec. europa. eu/europeaid/ sites/ devco/files/global-mapping study 2016.pdf) site visited on 20/05/2019.

Hurrell, R. F. (2021). Iron Fortification Practices and Implications for Iron Addition to Salt. *The Journal of Nutrition* 151(Suppl 1): 3S–14S.

Kavishe, F. P. and Harris, A. (2017). Report on Tanzania's first national summit on food fortification in Tanzania 2017. In: Proceedings of the revisiting commitments from the 2015 Arusha summit. 23-24 August 2017, Arusha Tanzania, pp 40.

Khamila, S., Sila, D. N. and Makokha, A. (2020). Compliance status and stability of vitamins and minerals in Fortified Maize Flour in Kenya. Scientific African, e00384. 8(2020):1-12. (https://www. Sciencedirect com/ science/ article/ pii/ S2468227620301228) site visited on 20/10/2020.

Kothari, C. (2004). Research Methodology: Methods and Techniques. New Age International (P) Limited, New Dheli. 418pp.

Kuong, K., Laillou, A., Chea, C., Chamnan, C., Berger, J. and 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): 51.

Luthringer, C. L., Rowe, L. A., Vossenaar, M. and Garrett, G. S. (2015). Regulatory monitoring of fortified foods: identifying barriers and good practices. *Global Health: Science and Practice 3*(3): 446-461.

Mark, H. E., Assiene, J. G., Luo, H., Nankap, M., Ndjebayi, A., Ngnie-Teta, I. and Engle-Stone, R. (2019). Monitoring of the National Oil and Wheat Flour Fortification Program in Cameroon Using a Program Impact Pathway Approach. *Current Developments in Nutrition* 3(8): 1-16.

Martin, N., Mokaya, J., Smith, E. G. and HKI (2016). Small and Medium Scale Fortification of maize flour in Kenya and Tanzania. (https://integrated nutritionconference.crs.org/sites/default/files/Day14.C2NMartinANF4WSM %20Scale%20Fortification%20Maize%20Flour%20Kenya-Tanzania.pdf)site visited on 12/5/2020.

Miller, D. M. (2008). Minerals. In: Damodaran, S., Parkin, K. L. and Fenemma, O. W. (Eds.) Fenemma's food chemistry, 4th edition. CRC Press, Boca Raton, FL, USA. 439–521.

Mkambula, P., Mbuya, M. N., Rowe, L. A., Sablah, M., Friesen, V. M., Chadha, M. and Gorstein, J. (2020). The Unfinished Agenda for Food Fortification in Low-and Middle-Income Countries: Quantifying Progress, Gaps and Potential Opportunities. *Nutrients* 12(2): 354.

National Bureau of Statistics (NBS) (Tanzania) and I.C.F Macro. (2011). Tanzania demographic and health survey 2010. Dar es Salaam: NBS and ICF Macro. (https://dhsprogram.com/pubs/pdf/fr243/fr243(24June2011)) site visited on 13/05/2020.

Noor, R. A., Abioye, A. I., Ulenga, N., Msham, S., Kaishozi, G. and Gunaratna, N. S, (2017) Large – scale wheat flour folic acid fortification program increases plasma folate levels among women of reproductive age in urban Tanzania. *Proceedings of the National Academy of Sciences of the United States of*

America 12(8): 1-16.

Nuzhat, H. (2004). Fortification of whole wheat flour with iron for the productions of unleavened flat bread (chapattis). (Doctoral dissertation, University of Agriculture Faisalabad).

Ogunmoyela, O. A., Adekoyeni, O., Aminu, F. and Umunna, L. O. (2013) A Critical Evaluation of Survey Results of Vitamin A and Fe Levels in the Mandatory Fortified Food Vehicles and Some Selected Processed Foods in Nigeria . *Official Journal of Nigerian Institute of Food Science and Technology* 31(2): 52 – 62.

Papathakis, C. P. and Pearson, E. K. (2012). Food fortification improves the intake of all fortified nutrients, but fails to meet the estimated dietary requirements for vitamins A and B6, riboflavin and zinc, in lactating South African women. *Public Health Nutrition* 15(10): 1810.

Rosado, L. J., Cassis, L., Solano, L. and Duarte-Vazquez, M. A., (2005). Nutrient addition to corn masa flour: effect on corn flour stability, nutrient loss, and acceptability of fortified corn tortillas. *Food and Nutrition Bulletin* 26: 266–272.

Saunders, M., Lewis, P. and Thornhill, A. (2009). *Research methods for business students*. Pearson education. Pitman Publishing imprint., London. 604pp.

Sharma, N., Sharma, S. and Singh, B. (2020). Stability evaluation of iron and vitamin A during processing and storage of fortified pasta. *Quality Assurance and Safety of Crops and Foods* 12(2): 50-60.

Smith, L., Alderman, H. and Aduayom, D. (2006). Food insecurity in Sub-Saharan Africa: New Estimates from Household Expenditure Surveys. Research Report. International Food Police Research Institute. Washington D.C. 146: 122pp.

Sunley, N. and Umunna, L. (2010). Strengthening monitoring and compliance within the South African Food Fortification Program. Johannesburg., South Africa, 122pp.

Tanzania Bureau of Standards (2018). Tanzania Standard on Fortified milled maize (corn) products - TZS 328. Tanzania Bureau of Standards, Dar es Salaam, Tanzania. 9pp.

TDHS, (2015-16). Demographic and Health Survey and Malaria Indicator Survey (2015-16). https://www.dhsprogram.com/pubs/pdf/SR233/SR233.pdf) site visited on 11/02/2020.

TFNC, (2014) Tanzania National Nutrition Survey. (https://www unicef.org/ esaro/Tanzania National Nutrition Survey 2014. Final report 18012015pdf) site visited on 17/07/2019.

Traore, T. (2008). Regional harmonization for sustainable food fortification program (ECOWAS regional feasibility study). *Ouagadougou, Burkina Faso: West African Health Organization*. (https://www.smarterfutures.net/wp-content/uploads/2013/12/ECOWASwide Fortification Report 02 09 Final.pdf) site visited on 12/5/2020.

UNICEF, (2019). The State of the World’s Children 2019. Children, Food and Nutrition: Growing well in a changing world. UNICEF, New York. (https://www.unicef.org/media/60806/file/SOWC) site visited on 10/02/2020

WHO, (2016). Fortification of maize flour and corn meal with vitamins and minerals. Geneva Switzerland: World Health Organization. (https://apps. who. int/ iris/ bitstream/ handle/10665/251902/9789241549936eng.pdf?sequ) site visited on 12/10/2019.

Wirth, J., Nichols, E., Mas’d, H., Barham, R., Johnson, Q. and Serdula, M. (2013). External Mill Monitoring of Wheat Flour Fortification Programs: An Approach for Program Managers Using Experiences from Jordan. *Nutrients* 5(11): 4741–4759.

Yusufali, R., Sunley, N., de Hoop, M. and Panagides, D. (2012). Flour fortification in South Africa: post-implementation survey of micronutrient levels at point of retail. *Food and nutrition bulletin 33*(4_suppl3): S321-S329.

Zhao, Y., Li, Z., Ross, A., Huang, Z., Chang, W., Ou-yang, K., and Wu, C. (2015). Determination of heavy metals in leather and fur by microwave plasma-atomic emission spectrometry. *Spectrochimica Acta Part B:* 112: 6–9.

Zimmerman, S., Baldwin, R., Codling, K., Hindle, P., Montgomery, S., Pachón, H. and Maberly, G. (2014). Mandatory policy: Most successful way to maximize fortification's effect on vitamin and mineral deficiency. *Indian Journal of Community Health* 26(Supp 2): 369-374.

CHAPTER FOUR

4.0 EXTENT OF INTERNAL IMPLEMENTATION OF QUALITY ASSURANCE AND QUALITY CONTROL PRACTICES BY SMALL SCALE PROCESSORS OF FORTIFIED MAIZE FLOUR

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Abstract

The aim of this study was to assess the extent of implementation of fortification practice (quality assurance and quality control) by processors to attain compliance. A descriptive cross sectional study was carried out between December 2019 and January 2020 in Ubungo district in Dar es Salaam region and Morogoro municipality in Morogoro regions involving 38 small scale processors. Data was collected through observational checklist and analysed using IBM SPSS ® version 20. Descriptive statistics was used to determine frequencies and percentages of implementation of fortification practices in cleaning and sanitation, personnel, written procedures or instructions on QA/QC, control of micronutrient premix, control of flour fortification processes and Control fortified flour. Results indicate that only 36.8% of warehouses and 42.1% of production areas were cleaned. It was also observed that, 26.3% of the premixes were kept open in production area close to milling machine where heat is generated and only 68.4% of fortified maize flour was stored over the pallet. Furthermore, it was observed that only 2.6% of processors have written instructions or procedures that guide them during fortification process to ensure quality and only 13.2% were able to conduct quality check of fortified maize flour to confirm the presence of micronutrients. It was concluded that, the implementation of quality assurance and quality control practices by small scale processors were poor. Strengthening of quality assurance and quality control practices to small scale processors is recommended in order to ensure that the targeted groups of people receive safe and quality fortified maize flour with adequate micronutrients.

Keywords: Fortification, Quality assurance, Quality control, Practice

4.1 Introduction

Implementation of fortification programme requires monitoring programme which involves quality control (QC) and quality assurance (QA) at both factory and regulatory level (Allen, 2006). The practice of QA/QC is necessary for the processors of fortified food to ensure processed food is of good quality and safe to consumers as well as adherence to the stipulated laws and regulations. The internal quality assurance at the factory involves quality of premix, fortification process, quality control of fortified maize flour. Some of quality control includes, iron spot test to determine level of added iron in fortified flour and quality of food packaging bags, receipt, storage and delivery, feeder calibration, records keeping and laboratory analysis (ECSA, 2007). QA/QC as part of internal monitoring removes all anomalies that when happen in the food production chain, reduces the level of compliance to the relevant regulation/laws (Luthringer, 2015) and should be practiced by both processors and regulators. The issue of QA/QC is not priorities for many food producers especially small scale processors which compromise health and safety of consumers. Lack of sufficient QA/QC by food producers in most low and middle income countries including Africa and Asia causes persistency under fortified food in the market (Luthringer, 2015).

QA/QC is mostly practiced by large processors living behind small and medium scale processors of which about 90% of processed food especially maize flour consumed by the majority of people are produced by small scale processors (Wilson, 2015) of which its QA/QC practices have not been evaluated. This is because small scale processors of fortified maize flour in Tanzania operates under voluntary basis and practicing of QA/QC is costly as it requires trained staff, well equipped facilities, capital and establishment and implementation of procedures for different activities performed in the food chain to attain quality. In Indonesia, small and medium scale salt processors account for 40% and do not have QC/QA control or any control check at factory level (WHO, 2011). This raises the concern on the level of compliance of food produced by small scale processors of fortified food.

QC/QA is mostly practiced by large companies who have modern equipment, well-educated and trained workers, although, not all large companies which have good quality control and quality assurance mechanism its final products comply with the stipulated standards. The self-reported quality control and quality assurance of large factories of maize flour, wheat flour, vegetable oil and sugar revealed that, 55% of samples were not fortified as per standard (Luthringer, 2015). Therefore implementation of QC/QA to all level of production should be emphasized and monitored to ensure the processed food comply with the recommend standards and is safe for consumption.

Despite the good progress made by the government of Tanzania on initiation of fortification to small scale processors, there is no specific guideline or manual for internal monitoring of fortified maize flour to small scale processor at production level. The manual for internal monitoring of fortified food in East, Central and Southern African Health Community (ECSA) members have been in place since 2007 but compliance of most of fortified food in ECSA member country were found to be low due inadequate use of existing manuals (ECSA, 2007). This manual demonstrates how to perform quality assurance at the mill including storage and management of the premix, use of suitable packaging and labeling, and records keeping on the use of premix in relation to flour produced. Therefore, the extent of implementation of QC/QA by small scale processors of fortified maize flour was assessed in line with ECSA manual and WHO guidelines using checklist which include cleaning and sanitation, personnel, written procedures or instructions for different activities, handling of micro-nutrient, maize flour fortification process and control of fortified maize flour.

4.2 Materials and Methods

4.2.1 Study design

A descriptive cross sectional study was carried out between December 2019 and January 2020 in Ubungo district in Dar es Salaam region and Morogoro Municipality in Morogoro region. This design was suitable because the study aimed to capture and collect particular data on maize flour fortification practices (extent of implementation of quality assurance and quality control) by small scale processors of fortified maize flour regarding premix handling, control of fortified product, fortification process, hygiene and cleaning. Data was collected from small scale processors who are under fortification programme in the study areas.

4.2.2 Study population

The study involved small scale processing facilities which process fortified maize flour located in Ubungo district and Morogoro municipality and was under operation during survey.

4.2.3 Sampling techniques and procedures

A purposive sampling technique was employed. This technique was considered to be appropriate because the factory which processing fortified maize flour in the study area were known and not all of them were under operation during research period due to shortage of raw materials, capitals and technical fault of machine.

4.2.4 Data collection

Data was collected using observation checklist by observing various processes on QA/QC undertaken by processor during fortification. This approach was appropriate as it allows the observer to explore in-depth the whole process and note relevant phenomena that revealed a clear picture of the problem under study. The checklist consists of the following main areas.

a) Cleaning and sanitation

In cleaning and sanitation four areas were observed which are production area, warehouse and staff facilities and toilets and cleaning of raw materials (maize).

b) Personnel

Hygiene as recommended in the standard, wearing protective clothes, and training records in the performed task were assessed.

c) Written procedures on QA/QC

Implementation of different procedures/instruction used to ensure proper implementation of QA/QC was observed. These include; receipt and storage of raw materials, receipt and storage of premix, feeder verification and micronutrients analysis.

d) Control of micronutrient premix

The following procedures were careful observed in this section; premix status , availability of updated premix inventory, appropriate storage condition, first in first out (FIFO) system and handling of premix in the fortification site.

e) Control of flour fortification

Three items were observed in this section; availability of feeder performance records, availability of adequate premix in the feeder during fortification and availability of records of maize flour produced/premix used.

f) Control fortified flour

In this area analysis of fortified maize flour using iron spot test or external laboratory, labelling of fortified maize flour according to standard, storage of fortified maize flour and use of first in first out system in dispatch were evaluated.

4.3 Statistical analysis

The data was analysed using Statistical Package for Social Sciences (IBM SPSS® Version 20). The data was fed into SPSS and simple descriptive statistic was performed to obtain frequency tables. Descriptive statistics such as frequency and percentage was used to summarize and describe data collected.

4.4 Results

4.4.1 Cleaning and sanitation

The result from Table 4.1 shows that cleaning and sanitation in the production area was implemented by 42.1% processors while only 36.8% of the warehouses were adequately cleaned. More than half of processors (60.5%) have cleaned staff facilities and toilets equipped with water and soap whereby cleaning of raw materials (maize) before processing was done by all processors.

Table 4. 1: Implementation of quality assurance and quality control by processors of fortified maize flour

Variables	Description	Frequency (N=38)	Percentage (%)
Cleaning and sanitation	Production area	16	42.1
	Warehouse	14	36.8
	Staff facilities and toilets	23	60.5
	Raw materials (maize)	38	100.0
Personnel	Personal Hygiene	18	47.4
	Wearing protective clothing	13	34.2
	Trained in the task they perform[3]	35	92.1
Written procedures	Instruction on receipt and storage of raw materials (maize)	1	2.6
	Availability of instruction for receipt and storage of premix	1	2.6
	Instruction of control of dosage equipment	1	2.6
	Instruction on micronutrients analysis	1	2.6

[3]Check the availability of training records or training certificate

4.4.2 Personnel

Personnel compliance in the area of hygiene was only implemented by 47.4% of processors (Table 4.1). Also it was found that only 34.2% of factory workers used personal protective equipment (PPE) during production while 65.8% operate without PPE as recommended in the standard. Furthermore, higher compliance (92.1%) was observed in the area of training.

4.4.3 Written procedures

Written procedures or instructions of various activities done at the factory to ensure quality of fortified maize flour were also assessed and the results indicated that only 2.6%

had written fortification instruction/ procedures to ensure QA/QC of fortified maize flour while 97.4% of processors operates without written procedure (Table 4.1).

4.4.4 Handling of micro-nutrients

The results of micronutrients handling at the factory as shown in table 4.2 indicated that the premix used in fortification for all factories were up-to-date and handled well in the processing area. Also it was found that only 10.5% of the visited factory had updated premix inventory log for storing records, 73.7% of the premix were stored under appropriate conditions as specified by manufacturer and the rest 26.3% were kept direct on the floor and open in the production area.

4.4.5 Maize flour fortification process

The result of maize flour fortification process as shown in Table 4.2 indicated that only 5.3% of processors had records of feeder performance and 76.3% had no records of maize flour produced against premix used. Furthermore feeders were adequately filled with micronutrients during fortification for all visited factory.

Table 4. 2: Implementation of quality assurance and quality control by processors of fortified maize flour

Variables	Description	Frequency (N=38)	Percentage (%)
Handling of micro-nutrient	Premix is up to date	38	100
	Premix inventory is up to date	4	10.5
	Premix is stored under appropriate conditions[2]	28	73.7
	First in first out system in place	38	100
	Premix is handled well in the fortification site	38	100
Maize flour fortification process	Records of feeder calibration available	2	5.3
	Premix in the feeder adequate during observation	38	100
	Records of maize flour produced/premix used	9	23.7
Control of fortified maize flour	Analysis of flour using iron spot test[4]	1	2.6
	Analysis of flour in external lab[5]	4	10.52
	Labelling meet specification	16	42.1
	Maize flour stored appropriately[1]	26	68.4
	First in first out applied to dispatch	38	100

[1]Products stored on the pallets and out of direct sunlight. [2] product stored in cool, dry and hygienic place. [4]availability of equipments for qualitative analysis of fortified maize flour, [5]availability of test report from external laboratory

4.4.6 Control of fortified maize flour

The control of fortified maize flour as indicated in Table 4.2 showed that only 2.6% of processor performs internal monitoring of fortified maize flour using iron spot test and 10.52% subcontract laboratory analysis to other institutions. It was observed that, 42.1% of fortified product complied in marking and labelling as per the recommended standard. It was also observed that, 68.4% of the processors stored their final product properly, while 31.6% were not stored over the pallets as indicated in the requirements of standard.

4.5 Discussions

4.5.1 Control of fortified maize flour

Effective implementations of fortification programme require proper internal and external monitoring of fortified product. Internal monitoring at the factory level requires periodic testing to ensure the desired micronutrients are available before released to the market. The obtained results in the currents study show that 97.4% of processors lack instruments for laboratory processors, which was higher than the one reported in Kenya whereby 30% of processors had capacity of performing internal quality check (Khamila *et al.*, 2019). Iron spot test is the most common and rapid test used to verify the presence of micronutrient in the flour.

Also, it was observed that, fortified maize flour was not stored according to the recommended standard. As shown in Table 4.2, only 68.4% of producers stored fortified maize flour appropriately and the remaining 31.6% were stored on the flour. This can leads to decrease in some micronutrients like folic acid and reduce shelf life of final product. A storage condition of fortified maize flour is one of the factors that determine compliance and shelf life of the flour **(**Philar *et al.,* 2005). According to the requirements of the standard, fortified maize flour should be stored in appropriate condition over pallet (Fellows *et al.* 1995) to avoid spoilage of the final product by dangerous moulds (TZS, 2018). Likewise, the proper storage of fortified flour improves retention of less stable micronutrients such as vitamins which tends to be affected by the moisture contents due to improper handling (Mark *et al.,* 2019).

According to (TZS, 2018) and (ECSA, 2007) manuals for commercial fortified maize flour, the flour should be labelled with fortification logo, name of the fortification mill/center, address, brand, micronutrients levels, batch number and production date.

This is contrary to the finding of the current study of which more than half of processor (57.9%) did not comply with the requirement of marking and labeling in the area of batch number and production date as per (TZS, 2018). This could be due to lack of training on the importance of internal quality assurance of fortified maize flour at the mill. Batch number and production date are the unique identifier of the specific product which are important during traceability of the product.

4.5.2 Handling of micronutrients premix

The obtained results of the current study where by 26.3% of premix were found stored direct in the floor and others were kept open in the production area where heat was generated during production was lower than the one reported in South Africa whereby 36.7% of the premix were stored properly as per supplier instructions (Danster-Christians, 2015). According to initiatives flour millers' toolkit, premix should be properly stored away from sunlight, excessive heat (Johnson, and Wesley 2010) and on palettes made of a suitable material (ECSA, 2007). Also, "first-in, first-out" basis and potential water damage as to improve retention of micronutrients such as vitamin B9 should be taken into consideration when handling micronutrients (Coelho, 2002; Dunn *et al.*, 2014; Kuong *et al.*, 2016). Quality of fortified maize flour is determined by quality of premix. Improper storage of premix could result in loss of some micronutrients such as vitamin B9 which will result to noncompliance of the produced flour. According to Luthringer *et al.*, (2015) recommended that once the premix is opened, exposure to light air and temperature should be minimized to avoid noncompliance of the flour due to drop of micronutrients. Also, warm and humid storage conditions including warehouses which are not climatically controlled affect the stability of micronutrients such as folic acid.

4.5.3 Cleaning

Cleaning is essential in every production processes in order to ensure safety and quality of final product. Un-cleaned conditions such as raw materials, production area, warehouse, staff facilities and toilet can be a cause of final product contamination. It is recommended in the standard that, all production area, equipment and the environment where food is processed, should be cleaned at regular intervals, to prevent it being a source of food contamination (TZS, 2018). In contrary, the survey in the current study observed more than half of production area (57.9%) and more than 63% of warehouses were not cleaned as some had accumulation of dust and flour around the building and above the processing equipment. This could be contributed by lack of training on importance of maintaining cleaning in processing area and lack of close monitoring by regulatory authorities. Building of flour or bran dust in the processing area or warehouse is a major cause of cross contamination of final product as the environment will attract breeding of insect, birds and rat which contaminate grain or stored flour with hairs, feathers and excrete (Fellows *et al.*, 1995). Also, all processors were observed to adhere with cleaning conditions of raw materials by removing physical contaminants such as weed seeds, stalks insect remains, sand, stones and rotten maize. Cleaning of maize before processing is important as it protects the milling equipment, quality of product and health of consumers.

4.5.4 Personnel

In the production processes, contamination can be caused by personnel if proper hygiene is not followed. Source of contamination can be through hair, nose, mouth and hands (EAS 39, 2000). To implement QA/QC at the mill, the standard required personnel working in the production area to wear proper PPE (TZS, 2018). In contrary to findings of this study more than 65% of workers were found not wearing proper PPE. This could be the result of lack of close monitoring of workers and inadequate training on hygiene and hygienic practice as recommended by the standard. According to UNIDO, (2004), personnel working in processing area should be provided with hygienic facilities including adequate clothing such as mask, hair cover and the cleanness of the same should be maintained to avoid contamination of the product (UNIDO, 2004). The protective clothes like hair cover protect final product from hair contamination which can stuck in the throat when ingested and lead to health problem. Also, wearing of mask is very important as the production process of maize flour generates organic dust in the air and causes respiratory problems when inhaled (Mohammadien *et al.*, 2013).

4.5.5 Maize flour fortification process

Fortification processes requires proper use of quality assurance/control at the mill to ensure premix is adequately available in the feeder during fortification and feeder is working properly (ECSA, 2007). The survey also analyzed the availability of the records of dosifier calibration and the obtained results (94.7%) of the processors not having records of dosifier calibration was higher than the one reported in Kenya whereby only 34.9% found not calibrating their dosifier (Khamila *et al.*, 2019). This could be due to lack of technical knowhow on how to check the performance of the dosifier including calibration. According to ECSA, (2007) feeder should be verified regularly under defined interval to ensure proper release of micronutrients and uniform distribution of the micronutrients in the final product which can be consistently available during storage and after food preparation.

4.5.6 Written procedures or instructions

Proper implementation of different procedures or written instruction is necessary in the factory. Lack of procedures or instruction on how to perform a certain work can result to inconsistency and unreliable result. Documented instructions includes information such as the aim of processing, detailed operation instructions (step by step), how to perform maintenance and shut down operations of the machine (Akyar, 2012). The current study revealed that, 97.4% of processors did not have written procedures or instruction for fortification process. This result is higher than the one reported by Mark *et al.* (2019) in Cameroon whereby 50% of processor had instruction on storage of premix and 100% had instruction for control of dosage equipment. Having detailed documented information/procedures is very important in the processing industry as it help processors to have uniform and consistency mode of production hence improve quality. It is difficult for the millers to be consistence in adherence to QA/QC of the fortified food without written instructions on the activities carried out during fortification. According to ESCA manual of 2007 instruction on how to receive and store raw materials, premix, feeder verification and micronutrients analysis is important for controlling quality of final products.

4.6 Conclusions

This study shows that, the level of implementation of quality assurance and quality control at factory was low especially in the area of internal and external analysis of maize flour at factory. The probable cause of this was lack of laboratory capacity and high cost of analyzing the flour using external laboratory. Also, lack of procedure/instruction of different activities performed during fortification as observed in 97.2% of processors caused most of them to store fortified maize flour and premix in un-appropriated storage condition which resulted to loss of micronutrients such as folic acid. Lack of training on production practices including cleaning and sanitation to workers working in production area lead to low level compliance.

4.7 Recommendations

Based on the finding of this study, it is recommended that training on quality assurance and quality control to be done to small scale processors in order to increase level of compliance of fortified maize flour with the recommended standard. Also, the government to introduce the specific guidelines or manual for monitoring of fortified maize flour for small scale processors in order to have identical system of monitoring the fortified flour.

REFERENCES

Akyar, I. (2012). Standard operating procedures (what are they good for?). Latest research into quality control 367-391.

Allen, L. H. (2006). New Approaches for Designing and Evaluating Food Fortification Programs. *The Journal of Nutrition,* 136(4): 1055–1058.

Coelho, M. (2002). Vitamin stability in premixes and feeds: A practical approach in ruminant diets. *In: Proceedings 13th Annual Florida Ruminant Nutrition Symposiu* 127: 145.

Danster-Christians, N. (2015). The knowledge, attitudes and practices regarding food fortification among mill managers and the contribution of maize meal to the micronutrient intake of a national sample of South African adults. Dissertation for Award of MSc Degree at Stellenbosch University, Matieland, South Africa, 42-66 pp.

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

East African Standard (2000). East Africa Standard on Hygiene in the food and drink manufacturing industry - Code of practice - EAS 39. East African Community. 23pp.

Erbaş, M., Sultan Arslan, A. A. and Durak, N. Food Safety Risks in Flour and Hygiene and Sanitation in Flour Mills for Producing Safe Flour. https://www.miller magazin.com-english//food-safety-risks-in-flour-and-hygiene-and sanitation-in-flour-mills-for-producing-safe-flour/.html. Site visited on 16/6/2020.

ECSA, (2007). Manual for internal monitoring of fortified maize flour first edition (https://ecsahc.org/wp-content/uploads/2017/06/Manual-for-Internal-Monitoring-of-Fortified-Maize-Flour.pdf) site visited on 12/04/2020.

Fellows, P., Axtell, B. L. and Dillon, M. (1995). Quality assurance for small-scale rural food industries (No. 117). Food and Agriculture Organization (http://www.fao.org/3/v5380e/v5380e06.htm) site visited on 14/06/2020.

Johnson, Q. W. and Wesley, A. S. (2010). Miller's Best/Enhanced Practices for Flour Fortification at the Flour Mill. *Food and Nutrition Bulletin* 31(1 suppl1): S75–S85.

Khamila, S., Ndaka, D. S., Makokha, A., Kyallo, F., Kinyanjui, P. K., Kanensi, O. J. and Mwai, J. (2019). Status of commercial maize milling industry and flour fortification in Kenya. *African Journal of Food Science* 13(3): 65-82.

Kuong, K., Laillou, A., Chea, C., Chamnan, C., Berger, J. and 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): 51.

Luthringer, C. L., Rowe, L. A., Vossenaar, M. and Garrett, G. S. (2015). Regulatory monitoring of fortified foods: identifying barriers and good practices. *Global Health: Science and Practice* 3(3): 446-461.

Mark, H. E., Assiene, J. G., Luo, H., Nankap, M., Ndjebayi, A., Ngnie-Teta, I. and Engle-Stone, R. (2019). Monitoring of the National Oil and Wheat Flour Fortification Program in Cameroon Using a Program Impact Pathway Approach. *Current developments in nutrition* 3(8).

Mohammadien, H. A., Hussein, M. T. and El-Sokkary, R. T. (2013). Effects of exposure to flour dust on respiratory symptoms and pulmonary function of mill workers. *Egyptian journal of chest diseases and tuberculosis* 62(4): 745-753.

Philar, R., Johnson, Q., Ranum, P., and Wesley, A. S. (2005). Small scale mill fortification manual. The Micronutrient Initiative. Ottawa, Canada. (https://www.nutitionintl.org/fr/content/userfiles/)sites/2/2017/10/SMALL SCALE-MILL.pdf) site visited on 21/05/2020.

Tanzania Bureau of Standards (2018). Tanzania Standard on Fortified milled maize (corn) products - TZS 328. Tanzania Bureau of Standards, Dar es Salaam, Tanzania. 9pp.

UNIDO, (2004). Small-scale Cereal Milling and Bakery Products Production methods, equipment and quality assurance practices. (https://www.unido.org/sites/ default/files/2009-04/Small scale cereal milling and bakery products 0.pdf) site visited on 29/9/2020.

Wilson, R. T. (2015). The soybean Value Chain in Tanzania A report from the Southern Highlands Food Systems. Programme. (http:// www. fao. org/ fileadmin/ userupload/ivc/PDF/ SFVC/Tanzania maize.pdf) site visited on 09/07/2020.

WHO, (2011). Regional Office for the Western Pacific. Meeting on Regulatory Monitoring of Salt and Flour Fortification Programmes in Asia, 27-29 September 2011 Manila Philippines, 1-77 pp.

CHAPTER FIVE

5.0 OVERALL CONCLUSIONS AND RECOMMENDATIONS

5.1 General Conclusions

Despite of initiatives done by the governments of Tanzania to eradicate the problem associated with micronutrients deficiencies, the compliance of fortified maize flour processed by small scale processors to the recommended standard is still low. This could be attributed by operation of small scale processors under voluntary basis as they are not abide with the laws and regulations to make sure the products are adequately fortified. Also lack of training on importance of fortification together with lack of analysis of final products before released to the market lead to circulation of noncompliance products to the market. Furthermore, the exposure of fortified maize flour sold in the market to direct sunlight lead to loss of micronutrients such as folic acid hence, low level of compliance. Moreover, lacks of technical capability on maintenance of dosifier during technical faults caused some of processors to process and pack the unfortified maize flour in the packing bags with fortification log.

5.2 Recommendations

Based on the finding of this study, the following are the recommendations to various stakeholders of fortified maize flour so as to improve quality and compliance of fortified maize flour.

i. Further studies be conducted to investigate the performance of dosifier to analyze the feeding rate in order to remove the inconsistency and under addition of micronutrients at production areas

ii. The government to introduce by laws which will govern all small scale processors of maize flour to fortify their products in order to introduce equal level in the playing field and hold noncompliant processors accountable.

iii. While waiting for the small scale processors to have capability of analyzing the product at the factory, the government through regulatory body to enhance the frequency of monitoring the fortified maize flour to the factory as well as in the market and to confirm its compliance.

iv. The government to introduce programme of frequent training to small scale processors, consumers and retailers on the benefit of fortification, fortification standards and proper storage of fortified flour in the retail outlets.

v. Government to have in place guidelines for internal monitoring of fortified maize flour processed by small scale processors.

APPENDICES

Appendix 1: Observational checklist used to collect data on implementation of Quality assurance and quality control

Factory name………………………………………………………………………………

Physical address…………………….…………………..……………………………………

ASPECT	OBSERVATIONS	
1.1. Cleaning and sanitation	**Implemented 'Yes'**	**Not implemented 'No'**
1.1.1. Production area		
1.1.2. Warehouse		
1.1.3. Staff facilities and toilets		
1.1.4. Raw materials (maize)		
Sub total		
1.2. Personnel		
1.2.1. Personal hygiene		
1.2.2. Wearing protective clothing		
1.2.3. Trained in the performed task they perform		
Sub total		
1.3. Written procedures or instructions for:-		
1.3.1. Receipt and storage of raw materials (Maize)		
1.3.2. Receipt and storage of premix/fortificant		
1.3.3. Control of dosifier		
1.3.4. Micronutrient analysis		
Subtotal		
2.0. Micronutrient premix		
2.1 Premix is up to date		
2.1. Premix inventory is up to date		
2.2. Is premix stored under adequate conditions?		
2.3. "First-in-first out" system used		

2.4. Premix is handled well in fortification site		
Sub total		
3. Maize flour fortification		
3.1. Records of feeder performance available		
3.2. Premix level in feeder adequate during observation		
3.3. Records of maize flour produced/premix used up to date		
Sub total		
4 Fortified maize flour		
4.1. Analysis of flour using iron spot test		
4.2. Analysis of flour in external laboratory		
4.3. Labeling meets specifications		
4.4. Fortified maize flour stored appropriately		
4.5. "First-in-first out" system applied to dispatch		
Sub total		
GRAND TOTAL		

(Thank you for your cooperation)

Appendix 2: Interviews guide for data collection

Start by explaining the ground rules as follows:

Before we start this discussion kindly feel free to share your views as I'm interested to know your thought and opinion. Therefore in this discussion there is no wrong or right answer.

Questions

1. Name of the processing facility…………………………………………….
2. Name ………………………………. Age: ……………………………..
3. Location…………………………………………………………………
4. What is your role in this processing facility? ……………………………..
5. What is your level of education……………………………………………
6. For your opinion why do we add micronutrient in food?...........................
7. How long have you been adding micronutrient in maize flour……………
8. Have you heard about national standard of maize flour fortification?

   a). Yes ………………………….(b). No……………………
9. What are the challenges, if any, you meet in ensuring fortified maize flour produced comply with the recommended standards
   (a) Awareness and attitudes on fortification
   (b) Laboratory capacity
   (c) Capital and technical capability
   (d) Skills of workers/personal expertise
   (e) Training
10. How can these challenges be overcome?

(Thank you for your cooperation)

Appendix 3: Sample recording form

1. Location:

(i)Ubungo district………….. (ii) Morogoro municipality……………………….

2. Ward: ……………………………………………….

3. Sampling Source…………………………………………..

a) Production ………………….b) Retail outlets…………..

4. Name of the processing plant………………………………

5. Date of sampling ………………….

6. Sample code number……………………

7. Laboratory result for the analyzed specific micronutrient

(i) Iron …………………………..

(ii) Zinc …………………………

(iii) Folic acid …………………..

Appendix 4: Summarized feedback from the interviewed small scale processors on the challenges that they are faced to ensure compliance to the recommended standards

S/	CLUE	RESPONDENTS ANSWERS

N		
1	Training	When they were asked about maize flour fortification standard six of the respondents said that: "………I have not trained regarding fortification or the recommend standard. Usually director attends those training but unfortunately they are not the one involved direct in production. I think for better performance training should be done also to all people involve in production".
2	Awareness and consumers attitudes on fortification	When they were asked why are they adding micronutrients to maize flour four respondent said that: "…….they are just micronutrients, I don't know their purpose because I haven't trained on it. I just add it as i have told" they also said that: "……..There are a lot of mills who are not under fortification programme as it is not mandated by the law. This cannot create equal level in the playing field for other processors of fortified maize flour as even those who are under fortification programme did not see the importance of doing it." "…………….Lasting under voluntary fortification will not produce the desired effect. The government needs to review fortification programme or introduce by law which govern all processors of fortified maize flour to operate under the same condition"
3	Laboratory capacity	Most of the respondents reported that: "………I don't have any instruments for analyzing the fortified maize flour. I just believe this dosifier perform as per standard. I wish I could analyze the flour to be sure of my product but I cannot afford the cost of buying instruments or analyzing it in the external laboratory"
4	Workers skills, capital and technical capability	Four of the respondents reported that: "……We don't have skills and technical capability when it comes to dosifier. We only depends on the provider of

		the dosifier on everything, even when technical fault occur we have to wait for him. I think they should start giving us technical capacity and skills regarding dosifier instead of relying on them we can do it alone. What if they quit this program? Will it be the end of fortifying maize flour?" "…………When technical fault occurs, technicians from the supplier are not there to correct the faulty, it takes some times, at this period processing of the flour is still going on"