



ORIGINAL RESEARCH ARTICLE

COMPLIANCE OF MAIZE MEAL TO FOOD SAFETY AND FOOD FORTIFICATION STANDARDS AT MARKET LEVEL IN KENYA

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ABSTRACT

Food fortification is the addition of micronutrients to foods. It is one of the interventions for the prevention and control of micronutrients deficiencies in Kenya. This study aimed to determine the compliance levels of maize meals to the national aflatoxin thresholds and the food fortification standards in Kenya.

Maize meal samples (597) were obtained from local markets outlets in 10 Counties which were purposively selected based on the high number of millers and high consumption of maize meal. The collected samples were sorted by brands and duplicates identified using batch numbers. Randomly selected samples of diverse brands per county, which were representative of the analytical lot, were homogenized using a blender before drawing the analytical sample. A total of 312 analytical samples were prepared. Samples were analyzed for aflatoxin using Elisa, vitamins A and B complex using HPLC and minerals using AAS.

Overall, 14.4% of the maize samples had total aflatoxin levels above the safety threshold of 10ppb, with some samples having very high levels (>100ppb). Kiambu County had the highest (29.8%) number of samples with aflatoxin content above the maximum threshold. Overall compliance to maize fortification standard was at 28.0%. Kwale County had the highest compliance to fortification standards at 38.9% while Kisumu County had the lowest (20.8%). Compared with earlier surveillance done by the Ministry of Health in 2017, there was an improvement in compliance to fortification standards from 16.0% to 28.0%.

Aflatoxin was detected across the 10 counties as an indication of food safety concerns. Compliance with food fortification standards is still low despite all the efforts put by both government and its partners. There is a need for concerted efforts to understand the main causes of the low compliance levels to develop targeted strategies for mitigation.

Key words: Aflatoxin, Compliance, Food fortification, Maize Meal, Standards

1.0 INTRODUCTION

Malnutrition contributes to about 45.0% of child mortality mostly in low and middle-income countries (World Health Organization, 2020). The immediate causes of malnutrition are inadequate food intake and disease while some of the underlying causes include poor maternal and child care practices, household food insecurity and inadequate health services (WHO, 2021). According to the 2014 Kenya Demographic and Health Survey (KDHS), 26.0% of children under five years are stunted, 11.0% are underweight and 4.0% are wasted (Kenya National Bureau of



Statistics, 2015). Trends of malnutrition among children under the age of five years from 1993 to 2014 show little improvement in stunting though there was a great improvement in wasting and underweight from 2009 to 2014 (KNBS, 2015). Children and women are the population group noted to suffer from a high prevalence of hidden hunger. According to a national micronutrient survey of 2011, more than one quarter (26.3%) of children below five years are reported to suffer from anaemia of which 21.8% have iron deficiency (ID). Vitamin A deficiency (VAD) including marginal deficiency was reported to be 61.8%. Zinc deficiency was the highest (81.6%) in children under five years. Approximately 21.9% of non-pregnant women of reproductive age were reported to suffer from anaemia while 21.3% had iron deficiency. Zinc deficiency of 79.9% was reported in non-pregnant women. Of all micronutrients, zinc deficiency was noted in all cohorts including men whose prevalence was reported to be 74.8% (Ministry of Health, 2011).

To reduce malnutrition in the Kenyan population, the health sector has employed both curative and preventive strategies. Among the preventive strategies is food fortification. Food Fortification is the practice of deliberately increasing the content of essential micronutrients (vitamins and minerals) in food to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health (WHO/FAO, 2006). Food fortification is considered a sustainable intervention because it can reach wider populations without changes in existing consumption patterns (Das et al., 2013). It is also considered to be cost-effective (Castillo-Lancellotti, Tur & Uauy, 2013).

Food Fortification in Kenya dates back to 1970 when voluntary salt iodization started. In 1978, the Iodine Deficiency Disorder (IDD) prevention and control legislation was passed. It became mandatory for salt meant for human consumption to be fortified with iodine. This intervention resulted in a reduction of the prevalence of the total goitre rate to below 7.0% (KEMRI, 2004). Efforts to fortify other food vehicles with micronutrients of public health significance started in early 2000. Fortification of wheat flour, maize meal, fats and oils was made mandatory through the amendment of the Food, Drugs and Chemical Substances Act of the Laws of Kenya CAP 254, Notice No 62 of June 2012. This law was amended again in July 2015 through Notice No. 157 (GoK, 2015). It states that; 'Packaged dry Milled maize products shall be fortified and conform to the requirements specified.

Maize is one of the main staple foods in Kenya and constitutes a significant part of the daily diet. On average individual consumption is reported at 69.5 kilograms of maize and its products (Humanitarian Data Exchange, 2019). Maize is taken either as whole grain or processed into flour by milling. Maize meal can be as whole grain flour or sifted maize flour whose bran and germ has been removed. Removal of bran and germ results in the loss of a significant amount of micronutrients. Considering the high consumption of maize meals, maize is an important vehicle for food fortification.

One of the challenges of the maize industry is aflatoxin contamination. A group of mycotoxins is produced by the fungi *Aspergillus flavus* and *Aspergillus parasiticus* under warm and humid climatic conditions (Villers P, 2008). Four major groups of aflatoxins, namely AFB1, AFB2, AFG1 and AFG2 are common in food supplies including in maize. Aflatoxins pose a significant safety issue in food and risk to human health (Council for Agricultural Science and Technology, 2003). Aflatoxins contamination has been reported in maize from different regions in Kenya. This includes Makueni and Kitui counties where the mean aflatoxin was reported at 17.8µg/Kg (Daniel et al., 2011). Cases of aflatoxicosis have been reported in Kenya. For instance, during January–June

2004, an outbreak in eastern Kenya resulted in 317 cases and 125 deaths (Azziz-Baumgartner E, 2005).

In Kenya, the Ministry of Health is responsible for the verification of compliance to the fortification standards and food safety issues. This is done through inspection and sampling for analysis. Iron, zinc and vitamin A are the “indicator micronutrients” of compliance for maize meal fortification. It is, however, important to analyse all the minerals and vitamins to confirm compliance with all the micronutrients stipulated in the fortification standards. This helps to identify whether or not the added micronutrients (premix) meet the national standard. This study aimed to determine the compliance levels of maize meals sampled from markets in 10 Counties in Kenya to the national aflatoxin thresholds and the national food fortification standards.

2.0 METHODOLOGY

2.1 County selection and training of Public Health Officers

Public health officers from the 10 counties (Kiambu, Nairobi, Nakuru, Elgeyo Marakwet, Uasin Gishu, Kisumu, Busia, Mombasa, Kwale and Kilifi) were trained on sample collection following government guidelines. This was coupled with a practical session to harmonize the sampling protocol across the Country.

2.1.1 Sampling

The sampling was done at the market outlet level from the kiosks, retail shops and supermarkets in March 2020. A sampling form was used to collect sample information including the brand name, batch number, date of manufacture, among others. A schematic diagram of the experimental design applied in this study is indicated in figure 1.

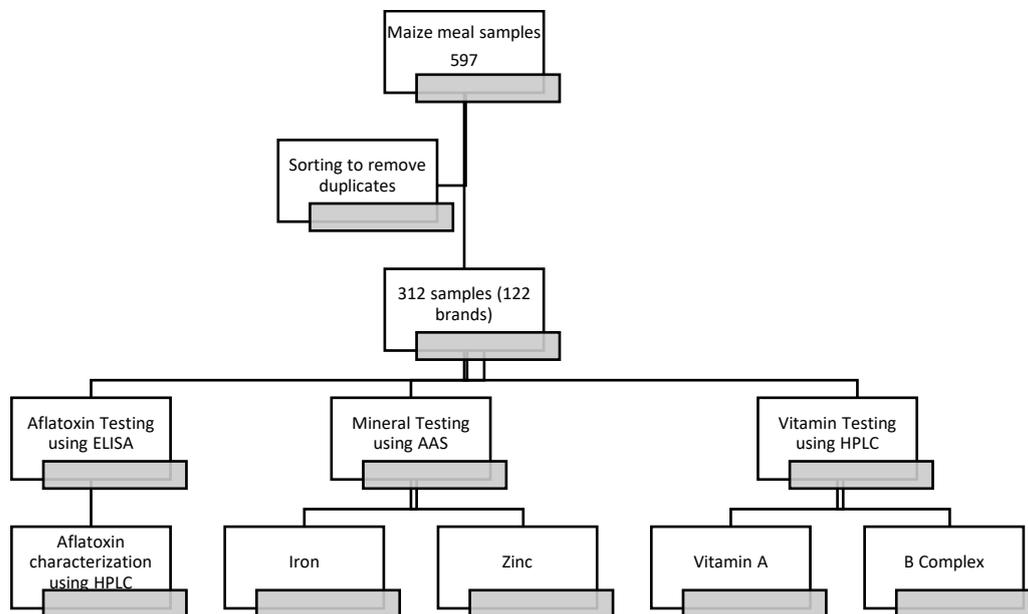


Figure 1: Experimental design

2.1.2 Sample Collection

Purposive random sampling was employed. A total number of 597 samples of maize were collected from the 10 Counties. Samples with similar batch numbers were sorted out to avoid



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duplication. Duplicate samples were composited and an analytical sample was drawn. Considering the cost of analysis and having a representative sample, 50.0% of the total number of samples from each county was analyzed. The selection of these samples was proportional to the number of samples available per Sub County. A total of 312 maize flour samples (comprising 122 brands) were analyzed as shown in figure 1. Table 1 provides a summary of the distribution of the maize meal samples among the 10 Counties of Kenya.

Table 1: Distribution of maize flour samples by County

S/No.	County	Samples collected from the field	Samples analyzed
1	Kiambu	112	58
2	Nairobi	96	50
3	Nakuru	84	43
4	Uasin Gishu	68	36
5	Elgeyo Marakwet	34	20
6	Kisumu	48	24
7	Busia	36	18
8	Mombasa	40	20
9	Kilifi	45	25
10	Kwale	34	18
	Total	597	312

2.1.3 Sample preparation

All individual samples selected for analysis were mixed using a blender to ensure homogeneity before drawing a laboratory sample. From the homogenized sample, three sub-samples were withdrawn. One sample was used for aflatoxin analysis, the second sample was used for vitamins mineral analysis while the third one was stored in hermetic bags for future reference.

2.2 Determination of total Aflatoxin

Total Aflatoxin Assay was determined using the manufacturer’s instructions. Two (2) grams of each sample was weighed into clean disinfected bottles and labelled with a unique sample number. Methanol solution (70%) was prepared with distilled water. The samples were extracted with 100ml of the 70% methanol solution (ratio of sample to extraction solvent was 1:5). The samples were mixed by shaking in a mechanical shaker and then filtered into clean centrifuge tubes using Whatman filter paper No.1. The residue on the filter paper was discarded and the filtrate retained for analysis.

Total Aflatoxin content was determined using the Elisa method. Standards of 0, 2.5, 5, 15 and 20 PBB were used to draw calibration curves against which the samples were read. The resultant



solutions in the microtiter wells were fed into a microtiter plate reader (Robonik Read well strip Elisa analyser) where the optical density of each microtiter well was read using a 450nm filter, which gave the amount of total aflatoxin present in each sample quantitatively.

2.3 Identification and quantification of types of aflatoxin

Six maize meal samples with the highest total aflatoxin were selected for aflatoxin characterisation. Identification and quantification of the different types of aflatoxin were determined using the method described by Scott & Trucksess, 1997. Approximately 10ml of the filtrate was transferred (equivalent to 1g of sample) into the glass syringe barrel for passage through the prepared immuno-affinity column at a flow rate of 2-3 ml/min. The column was first washed with 10ml of distilled water followed by elution of aflatoxins from the column with HPLC grade methanol. All of the methanol elution was collected and diluted with 1 ml of distilled water before injection into the HPLC system. The HPLC conditions included: Column: Zorbax Eclipse Plus C18, 4.6 x 150 mm x 5 µm; Column Temperature: 40 °C; Mobile Phase A: 1L water containing 238 mg KBr and 700 µL 4M HNO₃; Mobile phase B: MeOH Isocratic: A : B = 50 : 50, 12min; Flow rate: 1.0 mL/min; Detection: Ex: 362 nm, Em: 455 nm, gain = 15 Injection: 20 µL; Electrochemical Current: 100 µA setting Reaction coil: 0.5 mm i.d.*34 cm long peek tubing (from the exit of KOBRA cell to the entrance of FLD).

2.4 Determination of minerals

The method described by Shongwe, (2007) was used to determine iron and zinc content in the maize meal samples. Four grams of the maize meal sample were weighed exactly in duplicate crucibles and charred over a hotplate until smoking ceased. The charred samples were placed in a furnace and incinerated at 550°C for 6 hours. The crucibles were then removed from the furnace and cooled. Approximately 5 mL 1N HNO₃ was then added to the ash and transferred into a 100 mL volumetric flask. The crucibles were then washed several times with 1N HNO₃ to ensure complete removal of the ash and filtered using Whatman® filter paper No. 541. The filtrate was then diluted to the 100ml mark with 1N HNO₃ for analysis.

Mineral content (iron and zinc) was determined using Atomic Absorption Spectroscopy (AAS). An AAS (Shimadzu AA-700, Japan) was used for iron analysis at 248.3 nm and zinc analysis at 213.9 nm. Calculation of concentration was done using standard curves made for each element. Certified reference samples of known concentration were used for quality control in each case.

2.5 Determination of vitamin A

The retinol content was determined using the method described by Zahar & Smith, 1990. Into a 50ml glass stoppered centrifuge tube, 5g of maize meal sample were added followed by 10ml of absolute ethanol containing 0.1% (w/v) ascorbic acid followed by 2ml 50% (w/v) potassium hydroxide (KOH). The tubes were stoppered, agitated carefully and placed in a water bath at 80°C for 20min. During this period, the tubes were agitated periodically to ensure the complete digestion of fat. After saponification, the tubes were cooled with running water and then placed in an ice-water bath. Approximately 15ml of hexane containing 0.01% (w/v) butylated hydroxytoluene (BHT) was added. The tubes were again stoppered and mixed vigorously with a vortex for 1 min, allowed to stand for 2 min, and again vortexed for 1 min. Approximately 5ml of cold water (1°C) was added into the tubes and inverted 10 times. Centrifugation was done at 1000 rpm at 1 g for 10 minutes. Approximately 10ml of the upper, organic layer was accurately removed by pipette into a rotary flask (tube) and the solvent was evaporated under vacuum at 40°C using a rotary evaporator. The residue was immediately re-dissolved in 1ml of methanol. For retinol standard solutions, the same procedure was followed as for samples but with the following



modifications: 1 ml of standard solution was used and 0.1ml peanut oil added before saponification (to protect retinol from oxidation); 5 ml of the upper phase was used and residue in 5 ml of methanol.

2.6 Vitamin A analysis

Vitamin A as retinol was determined using HPLC. The chromatographic experiment of the residue from sample extraction and the standards were determined using SHIMADZU HPLC NEXERA UFLC, Japan equipped with a SIL-20HT auto-sampler, SPD-M20A diode array detector and a quaternary pump LC-20AD. The mobile phase of methanol: water (95:5) was used with a flow rate of 1 ml/min and injection volume of 20ul. Column C-18 ODS size 250mm X 4.6mm X 0.5 um. Model 2DA series was used and detection was done at 325 nm.

2.7 Determination of B Vitamins

Vitamin B complex was determined following the method described by Ekinici & Kadakal, 2005. Five (5) grams of the samples were weighed in a 50ml falcon tube. The samples were then mixed with 20mls of acidified deionized water and extraction was enhanced using a mechanical shaker for one hour. The samples were then centrifuged for 10 minutes at a speed of 2500 rpm and an acceleration of 2g. The supernatant was then filtered using syringe filters 25mm 0.45µm and 1.5 mls collected in the HPLC vial ready for analysis.

Vitamin B complex was determined using HPLC. Chromatographic experiments were conducted using SHIMADZU HPLC NEXERA UFLC liquid chromatograph (LC), Japan equipped with a SIL-20HT auto-sampler, SPD-M20A diode array detector and a quaternary pump LC-20AD. A binary gradient method was used. The mobile phase channel A was 100 mM KH₂PO₄ (pH = 7.0), mobile phase channel B was methanol and the flow rate was 1.0 mL/min. The injection volume was 20µL, the column temperature was at 400 C and detection was done at 250 nm. The column used in the study was: 5-µm SUPELCO C-18 stationary phase in 4.6 mm x 250 mm. Vitamin standards were obtained from Sigma Aldrich (UK).

3.0 RESULTS

3.1 Food safety in maize meal

Out of 312 samples of maize meal analysed, 85.6% complied with aflatoxin standards of less than 10ppb (Figure 2). Out of these, 54.4% had aflatoxin level below detectable limits while 29.2% had aflatoxin below 10 ppb. County disparities were observed, with Kiambu County having the highest (29.8%) levels of non-conformity to aflatoxin standards while Mombasa County had the lowest proportion of contaminated maize meal samples (5.0%). The high non-conformity rates in Kiambu may be attributed to the presence of many small mills in the area as opposed to Mombasa which mostly has large mills with adequate quality control measures in place. Non-conformity to the aflatoxin limits required is an indication of the dangers posed to consumers of the maize flour in the country (Nabwire et al., 2020).

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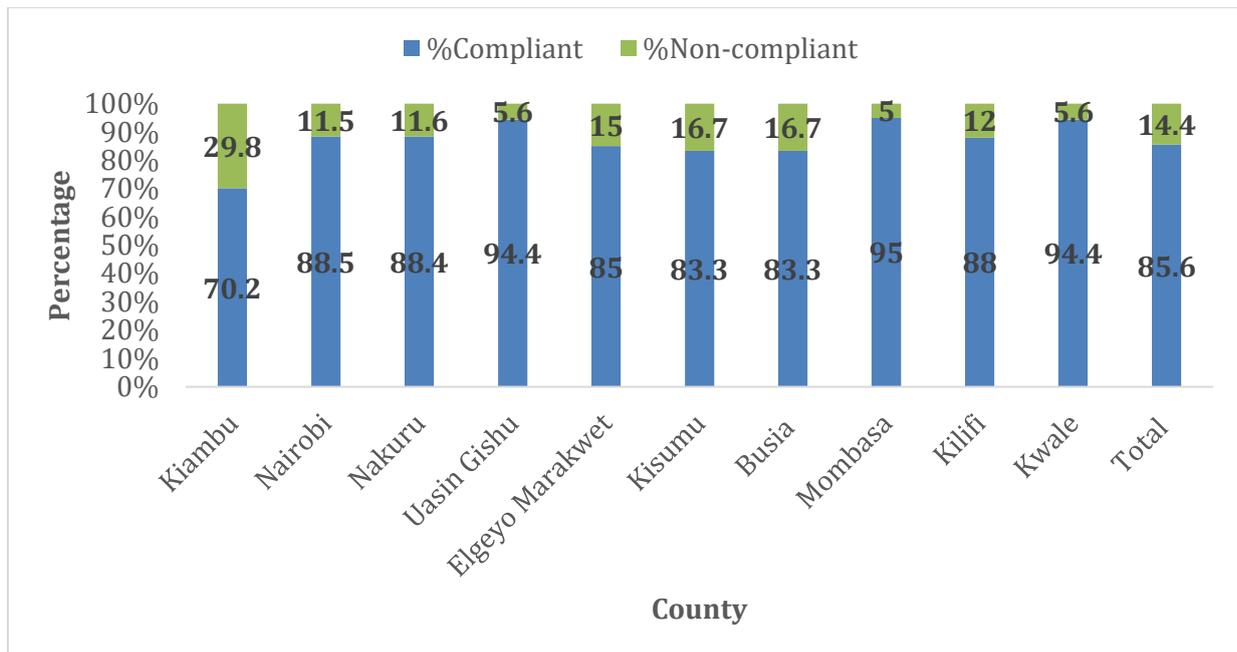


Figure 2: The proportion of maize meal samples with or without aflatoxin by county

3.2 Aflatoxin characterization in maize meal

All four types of aflatoxins (B1, B2, G1 and G2) were identified in the maize meal samples (Table 2). This is a clear indication of the safety concerns with regard to the consumption of maize flour in the country (Nabwire et al., 2020). The availability of all 4 types of aflatoxins in the samples analysed presents serious health challenges to the population who consume these products (Mahato et al., 2019). The most prevalent type of aflatoxin was B2 which was detected in all the samples followed by G1 detected in five samples. Aflatoxin B1 and G2 were detected in four out of the six maize samples. From the six samples analysed for the different types of aflatoxin, B1 ranged from non-detectable levels to 4.25ppb, B2 ranged from 0.45-14.12ppb, G1 ranged from non-detectable to 1.86 while G2 ranged from Non-detectable to 4.27ppb.

Table 2: Aflatoxin types identified in maize meal samples

Sample ID	Type and quantity (ppb) of aflatoxin identified in maize meal				
	Region	B1	B2	G1	G2
121	Kiambu	ND	1.09	1.86	0.18
225	Nairobi	1.14	14.12	0.96	4.27
245	Nairobi	4.25	1.07	0.23	0.48
282	Nairobi	1.02	0.45	0.21	ND
714	Kisumu	0.67	0.62	0.02	0.21
1019	Kilifi	ND	0.91	ND	ND

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Food safety remains a major concern in maize meals as aflatoxin was detected in all 10 counties. Detection of all aflatoxin types B1, B2, G1 and G2 in the maize meal samples was an indication of the high levels of maize contamination in Kenya. This compares with the study done by George, et al., 2019 where more than half of the maize grain samples collected from farmers’ fields in Eastern and South Western regions of Kenya had aflatoxin B1 levels exceeding maximum tolerable limits in the East African Community (EAC) of 5ppb. Other studies done in Ghana, showed high levels of contamination of maize from the markets with the different types of aflatoxins (Kortei et al., 2021). The presence of different types of aflatoxins in the maize flour is an indicator to the quality of raw materials used in the industry and measures to curb early infestation on maize from the farms to the stores need to be put in place.

3.3 Compliance to food fortification in maize meal

3.3.1 Iron content

Considering all the Counties, two thirds (66.7%) of the total maize meal samples analysed did not comply with the required iron levels of >21mg/Kg as per the food fortification standards established by KEBS (Figure 3). Despite the overall poor compliance to iron standards, the counties of Nairobi, Elgeyo Marakwet and Kwale Counties had high compliance rates of 90%, 72.2% and 57.7% respectively. The rest of the counties had low compliance rates ranging from 9.8% to 48%. The variations in compliance levels could be a pointer to the lack of adequate regulation of fortified foods (Luthringer, Rowe, Vossenaar, & Garrett, 2015). This variation in compliance levels is an indication that the different population sets consuming the products are not getting the same benefit despite the availability of fortification standards.

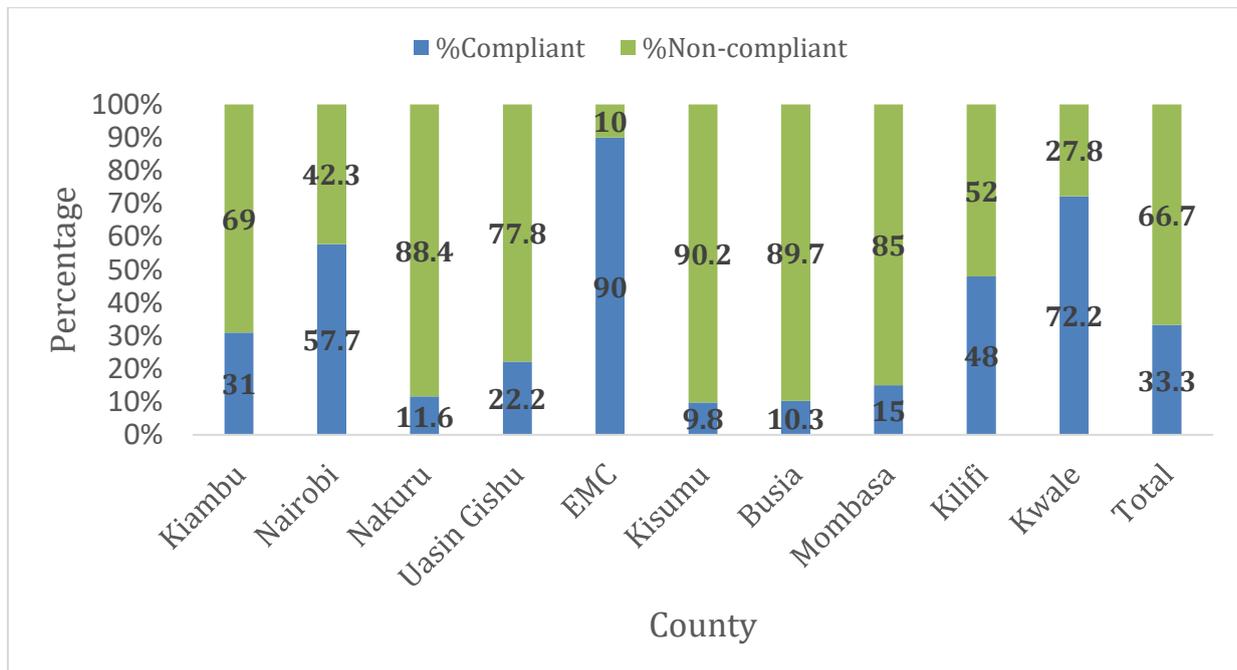


Figure 3: Iron content in maize meal

Figure 4 shows the distribution of iron content in the individual maize samples. Most of the samples are below the 21mg/kg cut off point an indication that the majority of the consumers are not benefitting from the fortification process. The highest amount of iron content in the maize meal

samples was reported in Kilifi County (39mg/kg) while the lowest amount was reported from Kiambu County (not detectable). The variation in fortification levels across different regions could hamper the gains the country has made in trying to lower micronutrient deficiencies (KNMS 2011, KNMS 1999).

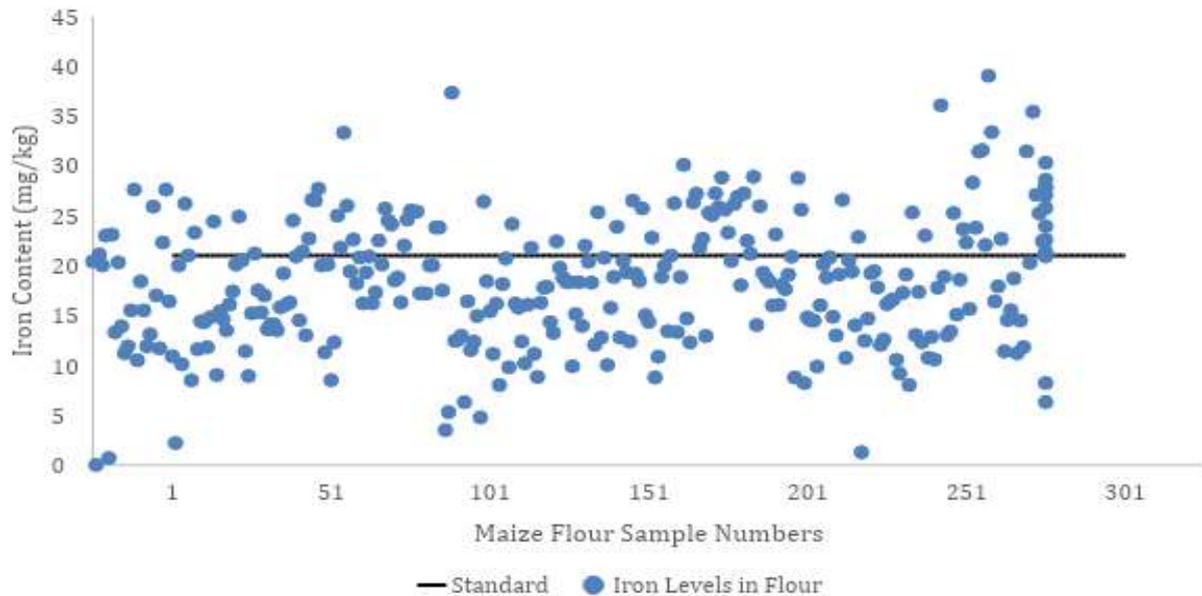


Figure 4: Scatter plot for iron content in maize meal samples

Compared with an earlier study conducted by the Ministry of Health, (MoH/GAIN, 2017) there was a decline in compliance to the iron content in fortified maize meals from 49% to 33.3%. This drop-in compliance is a pointer in the wrong direction given the potential benefit of lowering anaemia prevalence from large scale food fortification programs where implementation has been done to scale (Rowe, 2020). However, more studies especially at the industry level are required to establish the processes and real causes of the low compliance levels. Further analysis of the premix used to fortify the maize flour is also needed to corroborate the results and give a conclusive reason for the low compliance levels. Low compliance levels of 18.2% for iron were observed in Nigeria (Ogunmoyela et al., 2013) an indication that the challenge of iron compliance may be cutting across the African continent.

3.3.2 Zinc content

As was the case for iron, zinc compliance to the set standards of 33 – 65 mg/kg was only observed in the 3 counties of Kilifi, Kisumu and Mombasa with compliance levels of 52%, 56.5, and 70% respectively. The overall compliance for the analysed maize flour samples for zinc was low at 33.9%. This does not argue well with the goal of the food fortification program which is to increase consumption of fortified foods in the country to lower the high zinc deficiency levels (KNMS, 2011). Zinc is a key element in human nutrition and with the high zinc deficiency levels in the country, food fortification is a potential avenue for the promotion of consumption of this nutrient. With the recorded low compliance levels, the potential benefit of a large scale fortification program could be lost (Mkambula et al., 2020).

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The levels of compliance to iron and zinc are similar an indication of the likelihood of similar challenges in the food industries across the counties with regards to food fortification. However, the variation in compliance levels across the counties is a pointer to unique challenges in the various counties that were sampled.

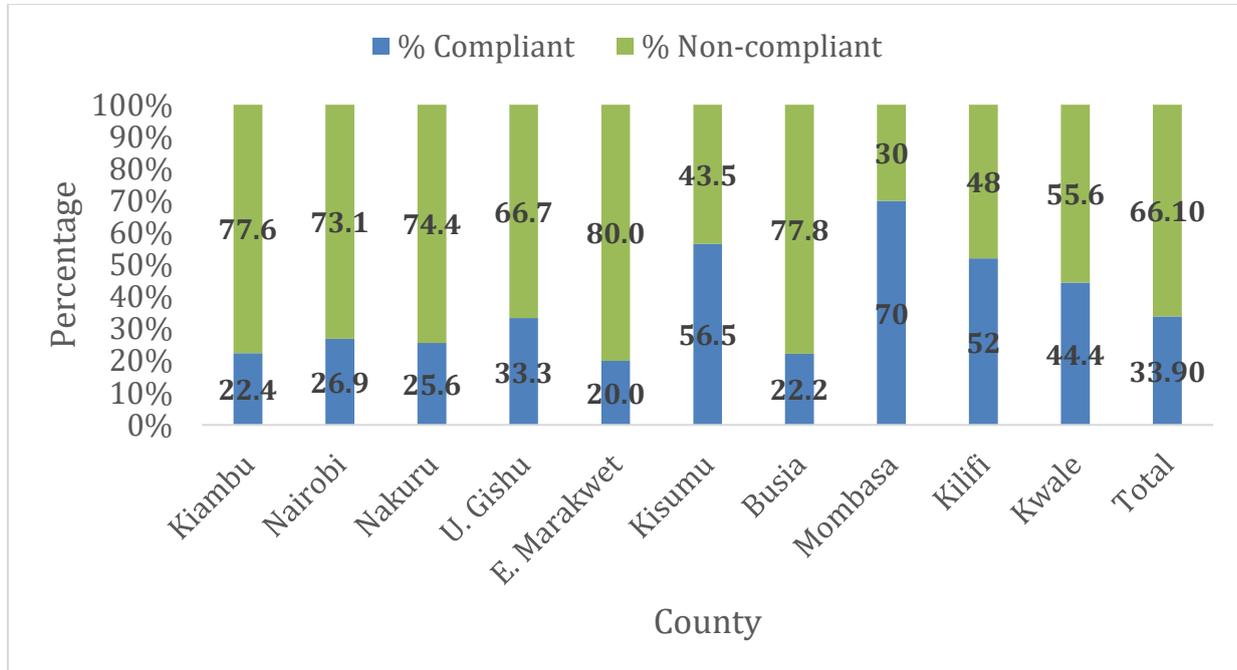


Figure 5: Percentage compliance to zinc fortification standards in maize flour

Figure 6 shows the distribution of zinc content in the individual maize samples. As noted in Figure 5, most of the samples had zinc content below the 33mg/kg while a few were above 65mg/kg thresholds set within the food fortification standard for zinc. About 34% of the samples lie within the set standard of 33-65mg/kg. The highest amount of zinc content in the maize meal samples was reported in Busia County (71.3mg/kg) while the lowest amount was reported in Kiambu County (0.35mg/kg).

The wide variations in levels of zinc across the counties point to the fortification compliance challenges experienced in the food industry. Quality gaps in the implementation of the large scale fortification program exist and these need to be addressed (Mkambula et al., 2020).

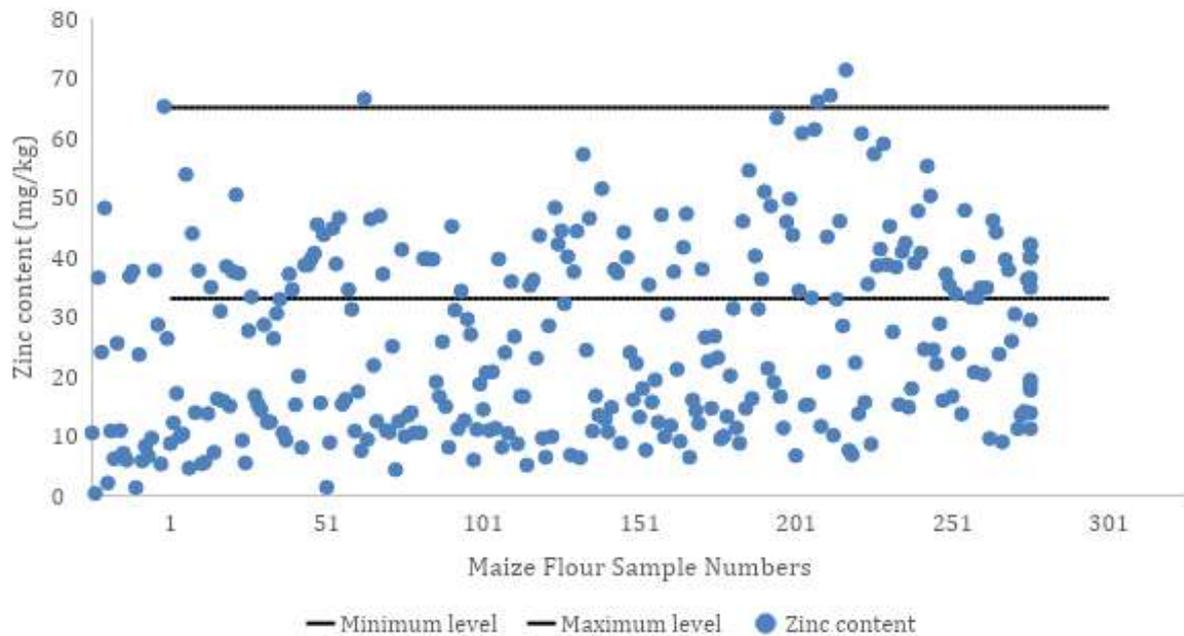


Figure 6: Scatter plot for zinc in maize flour samples

The current compliance levels for zinc at 33.9% are similar to the findings of a study conducted by MOH and GAIN (MoH/GAIN, 2017), which reported compliance levels of 34%.

3.3.3 Vitamin A

The overall compliance for vitamin A in maize meals was about thirty percent (29.9%) as shown in Figure 7 below. Most samples were non-compliant to vitamin A fortification standard of 0.5-1.4mg/kg. Uasin Gishu County reported the highest compliance rate at 44.7% followed by Kiambu County with 37.9% while Kilifi County had the lowest compliance rate at 16%.

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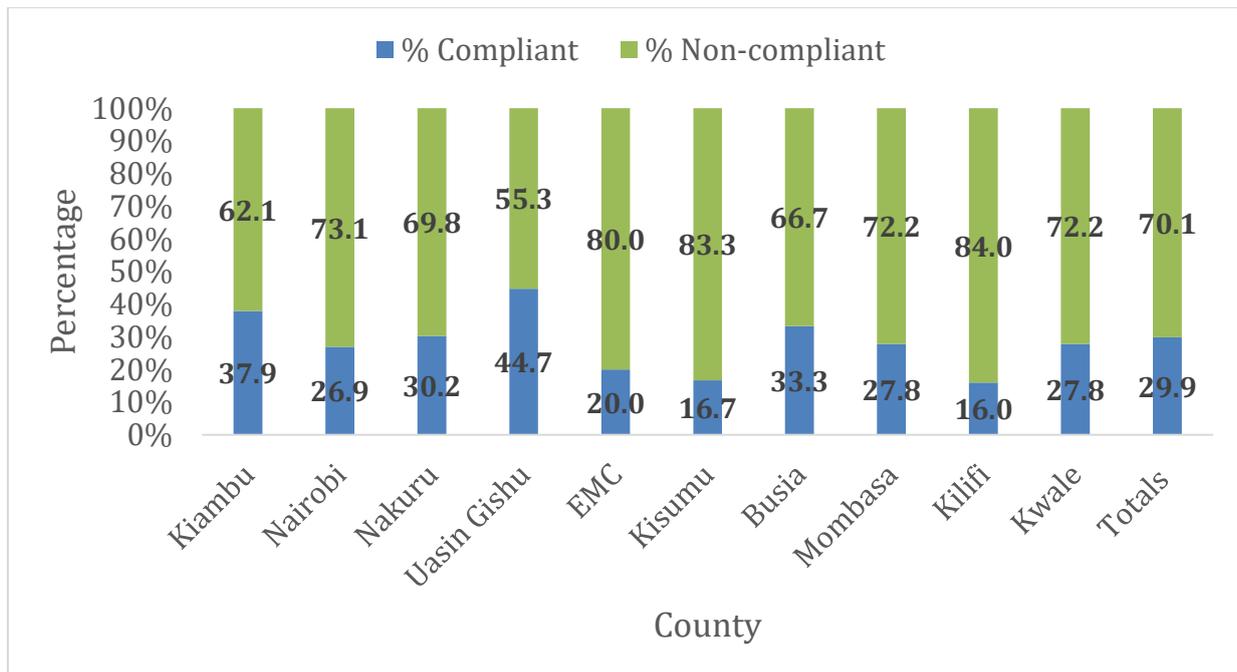


Figure 7: Percentage compliance to vitamin A fortification standards in maize flour

Figure 8 shows the distribution of vitamin A content in the individual maize samples. Most of the samples were below the 0.5mg/kg threshold while a few were above 1.4mg/kg. About a third of the samples had vitamin A content within the set standard of 0.5-1.4mg/kg. Nairobi County registered the highest amount of vitamin A content in the maize samples at 4.03mg/kg while many samples from various Counties had Vitamin A content below the detectable limits. The low compliance levels for vitamin A could be due to several factors one of them being the sensitivity of the vitamin to light and oxygen. Studies have demonstrated losses of up to 40% of vitamin A during the processing and storage periods (Ohanenye et al., 2021). In a study conducted in Malawi, losses of up to 61% of vitamin A along the supply chain were reported in maize flour (Ulemu, Ishmael, & Lawrence, 2016). This, therefore, calls for proper storage conditions for the fortified foods and education of consumers on the need to maintain the integrity of the packaging materials during use at the household level to ensure vitamin A availability.

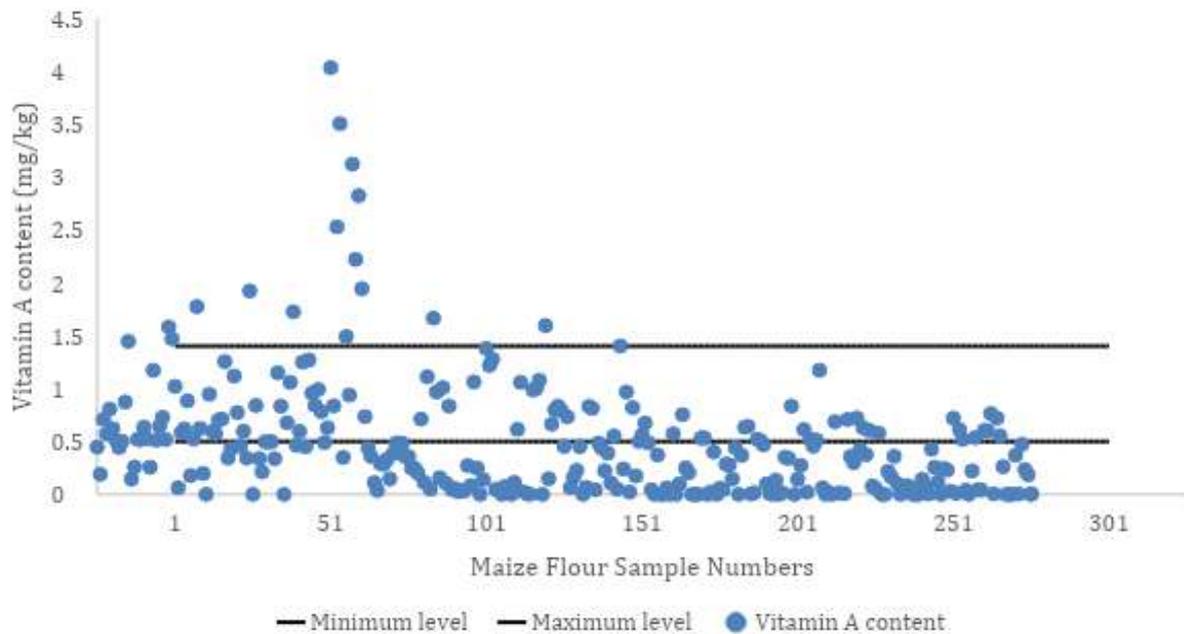


Figure 8: Scatter plot for vitamin A in maize flour samples

There was noted improvement in compliance to vitamin A fortification standard from 23% reported by MoH/GAIN, 2017 study as compared to 29.9% reported in this study.

3.3.4 Vitamin B1

Most of the maize meal samples (84.4%) were compliant to Vitamin B1 fortification standards (Figure 9). However, Mombasa County had high non-compliance levels, with 80% of samples not meeting the required standards. All the samples from Nairobi, Nakuru and Kwale were compliant to vitamin B1 content.

Food safety and food fortification standards

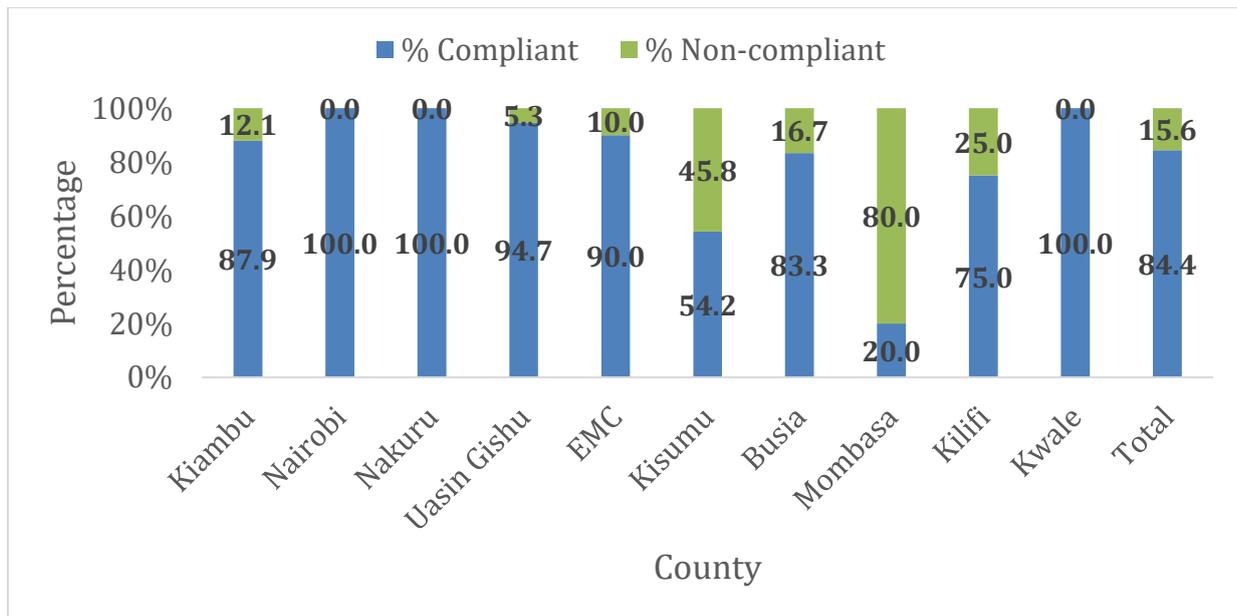


Figure 9: Vitamin B1 content in maize meal

Figure 10 shows the distribution and content of Vitamin B1 in the individual maize samples. Most of the samples were above the minimum set standard of 3mg of B1 per kg of maize flour. The highest amount of vitamin B1 content in the maize samples was reported in Kilifi County (503.12mg/kg) while some counties registered non-detectable amounts. The high compliance levels for the B vitamins is a good sign for the potential benefits that the consumers of these products could get.

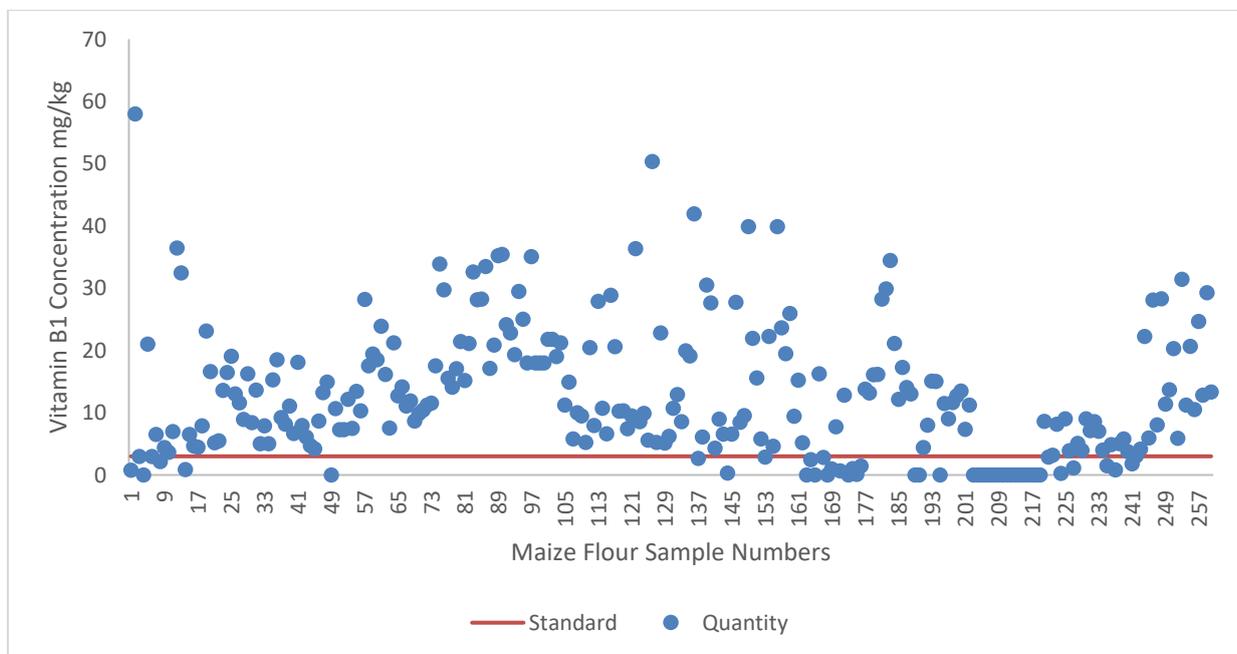


Figure 10: Scatter plot for vitamin B1 content in maize meal

3.3.5 Vitamin B2

Most of the maize flour samples were compliant to vitamin B2 content (72.8%) (Figure 11). However, Kwale County had the highest non-compliance rate (87.5%). All the samples from Elgeyo-Marakwet, Kisumu and Busia were compliant to vitamin B1 standards.

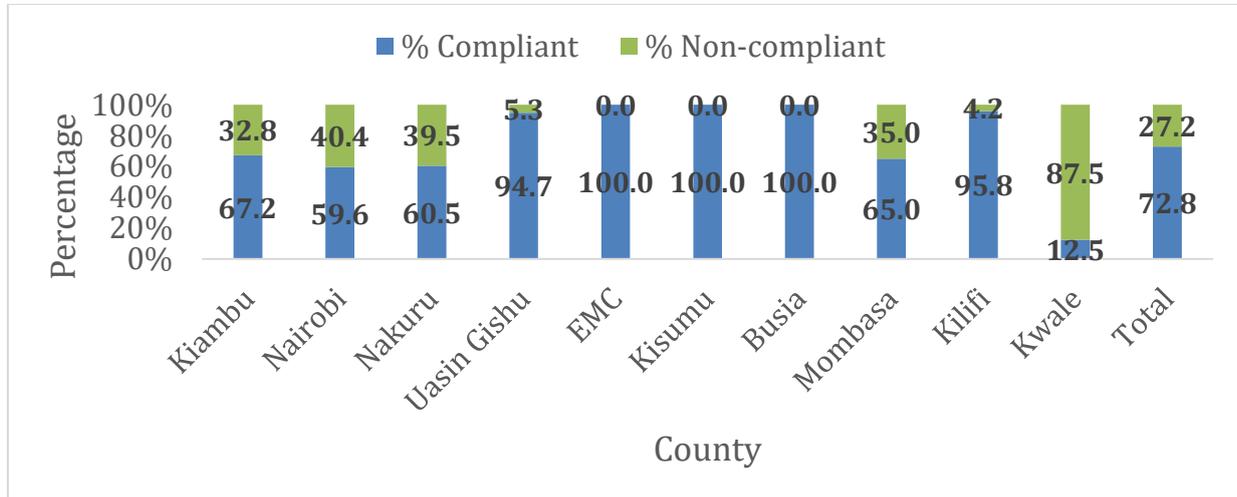


Figure 11: Vitamin B2 content in maize meal

Figure 12 shows the distribution and vitamin B2 content in the individual maize samples. Most of the samples were above the minimum threshold (2mg/kg). The highest amount of vitamin B2 content in the maize samples was reported in Kiambu County (1049.31mg/kg).

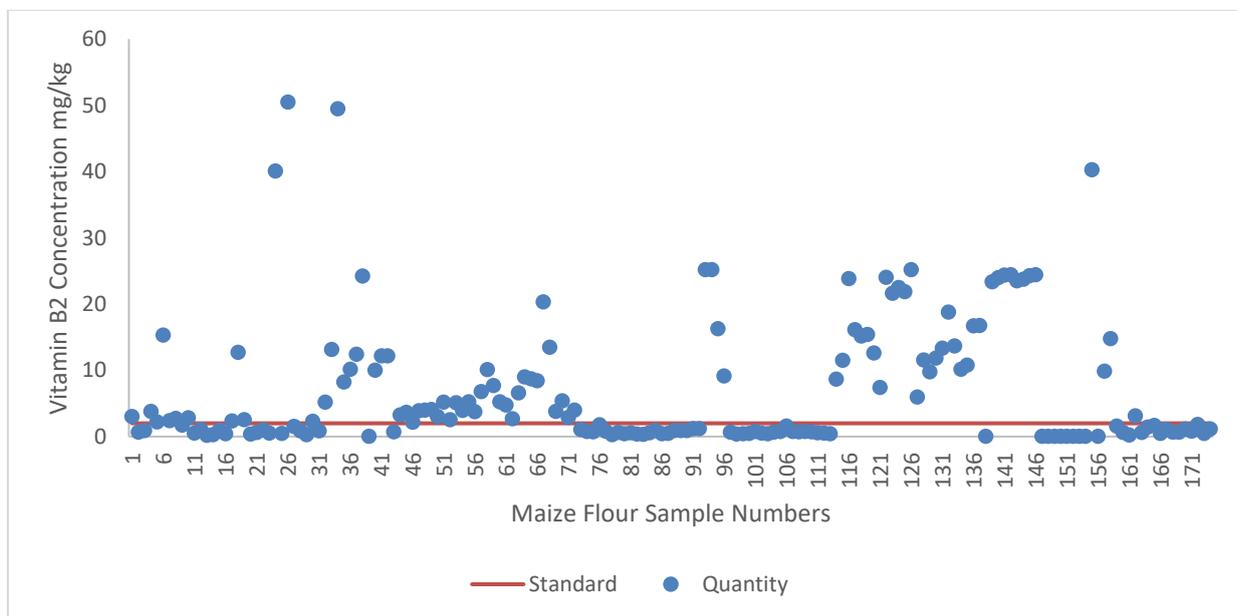


Figure 12: Scatter plot for vitamin B2 in maize meal

3.3.6 Vitamin B3

The same trend of Vitamin B2 was noted with vitamin B3 where most of the maize meal samples were compliant (80.3%) to the fortification standard (Figure 13). However, Uasin Gishu County registered the highest non-compliance (68.4%). All the samples from Kisumu County were compliant with vitamin B3.

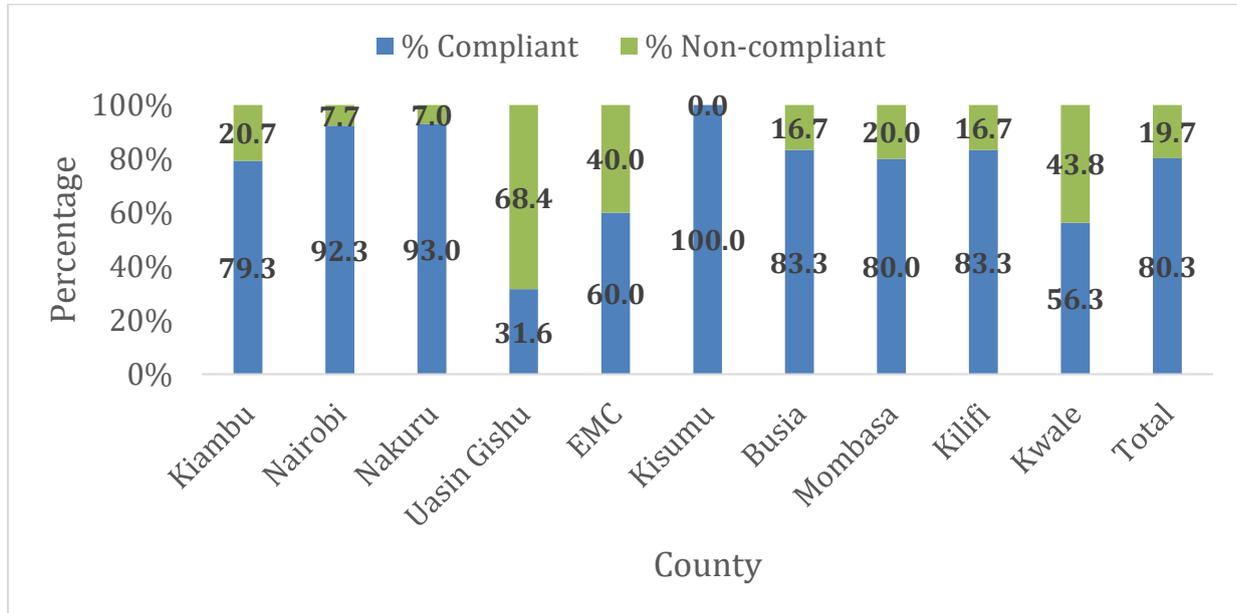


Figure 13: The level of vitamin B3 in maize flour

Figure 14 shows the distribution and vitamin B3 content in the individual maize samples. Most of the samples were above the minimum threshold limit (14.9mg/kg).

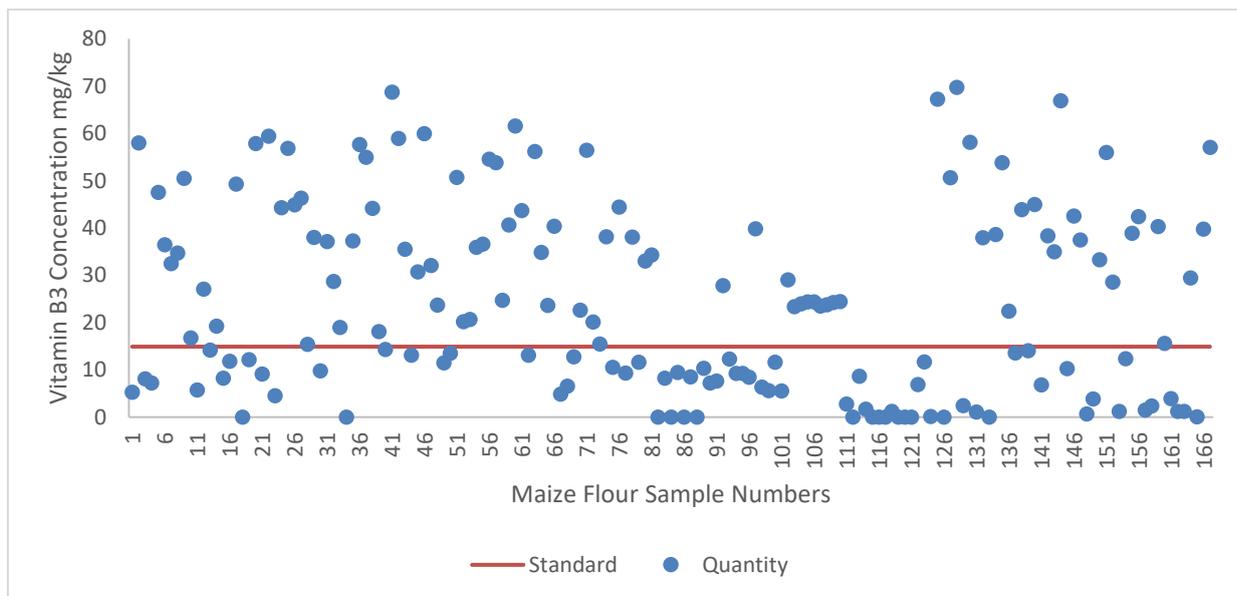


Figure 14: Scatter plot for vitamin B3 in maize meal

3.3.7 Vitamin B6

Most of the maize meal samples were compliant (79.8%) to vitamin B6 standards across all the counties (Figure 15). All the samples from Nakuru and Kwale were compliant with the requirements of vitamin B6 level though Kilifi County registered dismal results (58.3% non-compliance).

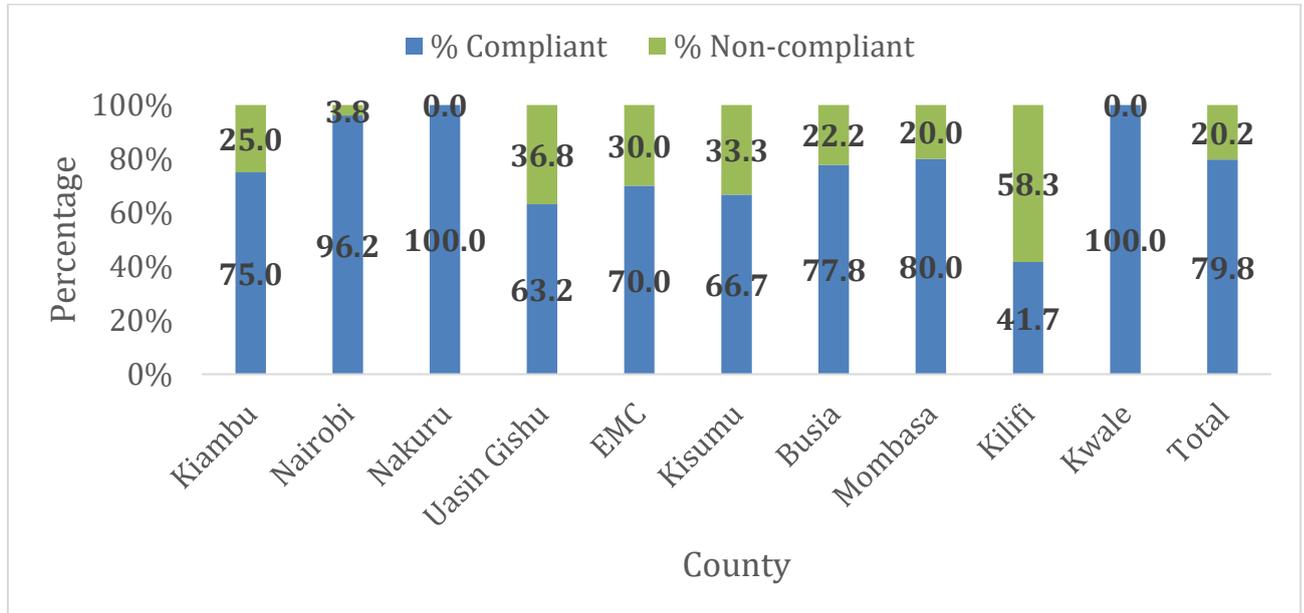


Figure 15: The level of vitamin B6 in maize flour

The scatter plot for Vitamin B6 (Figure 16) shows that most of the samples were above the minimum level (2mg/kg). The highest amount of vitamin B6 content in the maize samples was reported in Kiambu County (190.71mg/kg) while the lowest (no detectable level) was registered in various Counties.

Food safety and food fortification standards

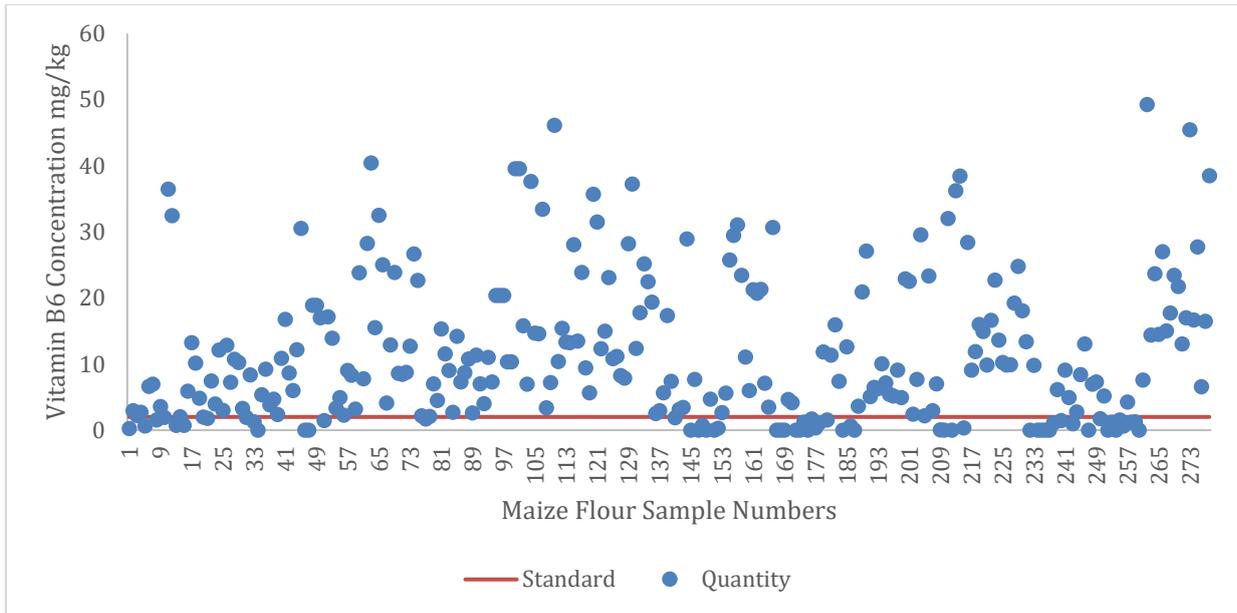


Figure 16: Scatter plot for vitamin B6 in maize meal

3.3.8 Folic Acid

The recommended range of folic acid in maize meals is between 0.6 - 1.7 mg/kg. Most of the maize meal samples (90.3%) failed to meet the set range as stipulated in the fortification standards of folic acid (Figure 17). The majority of the maize meal samples were above the upper limit while a few were below the lower limit. About a third (34.6%) of the maize meal samples in Nairobi County was within the expected range of added folic acid.

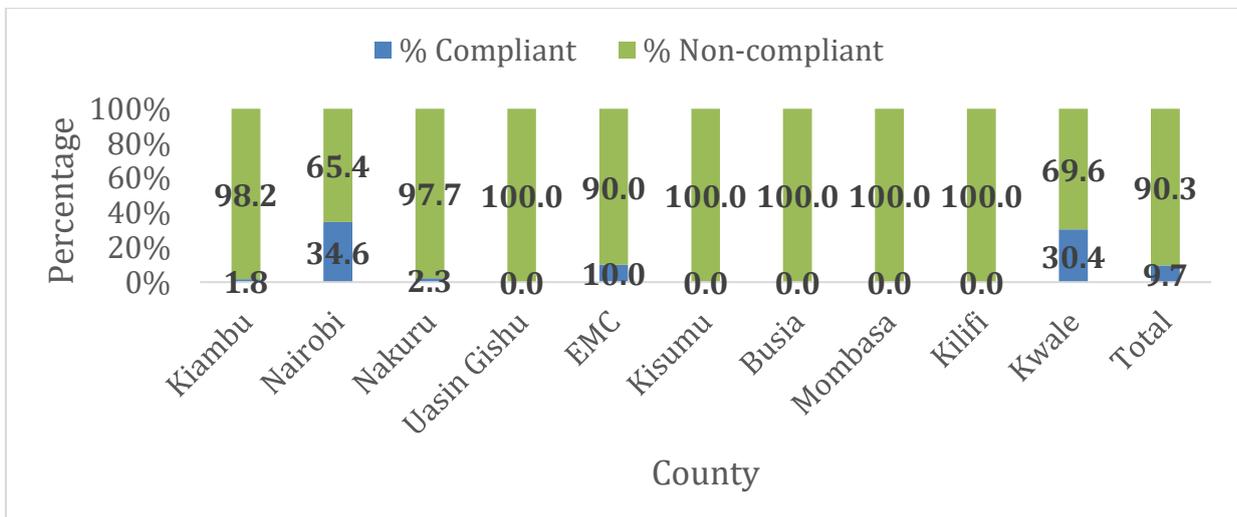


Figure 17: The level of Folic acid in maize flour

Figure 18 shows the distribution and content of folic acid in the individual maize meal samples. Most of the samples were outside the set range of between 0.6mg/kg and 1.7mg/kg. Less than ten percent (9.7%) of the samples had folic acid within the set standard of 0.6-1.7mg/kg.

Food safety and food fortification standards

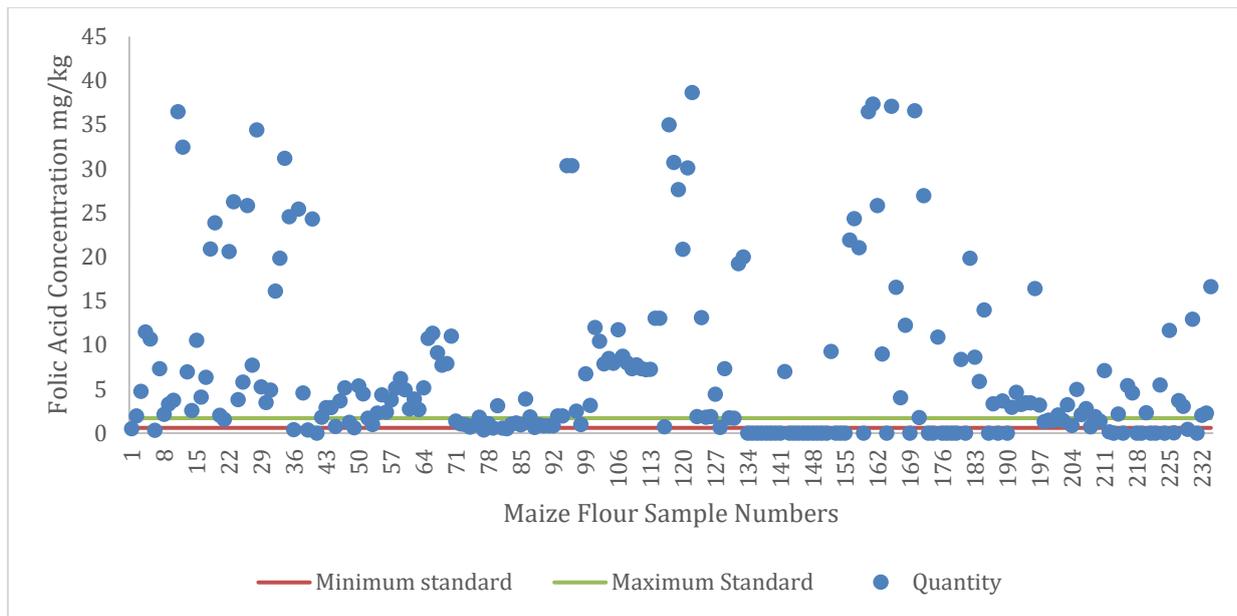


Figure 18: Scatter plot for folic acid in maize flour

3.4 Overall Compliance to fortification standards for maize meal

As indicated in Figure 19, about 28.0% of maize flour samples were compliant with the maize fortification standard for any two-indicator micronutrient (iron, zinc and vitamin A). Kwale County reported the highest compliance at 38.9% followed by Kilifi County (36.0%) while Kisumu County reported the lowest compliance rate (20.8%).

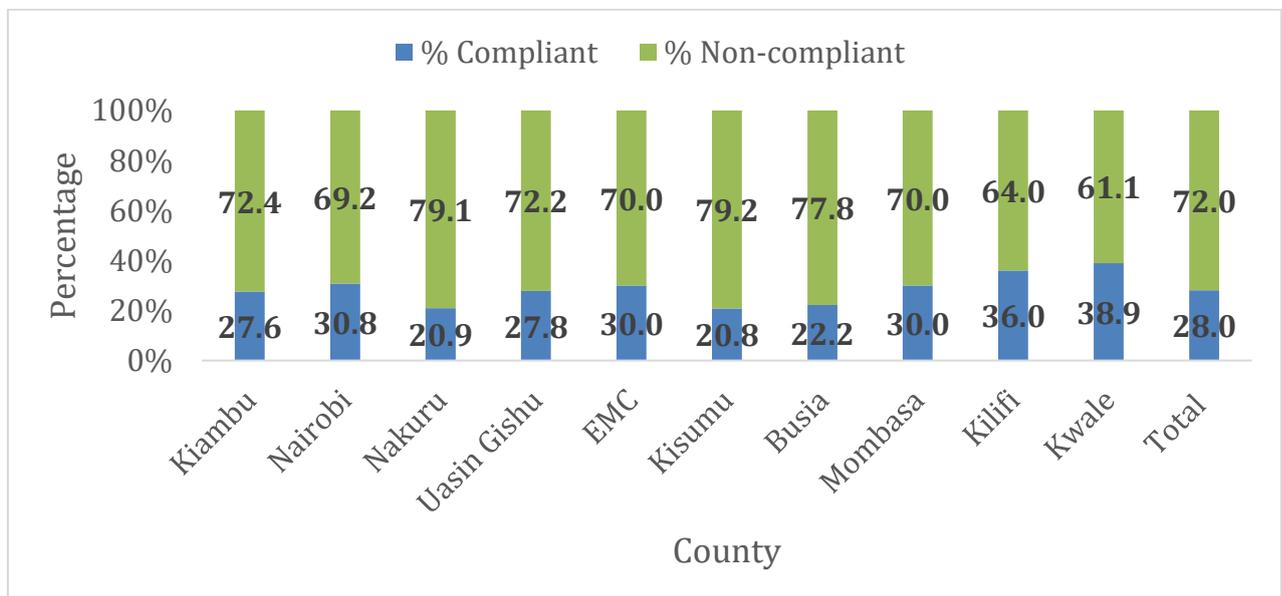


Figure 19: The fortification compliance level in maize flour

Compliance with food fortification standards is still low despite all the efforts put by both government and partners. Overall compliance improved from the 16.0% reported by MoH/GAIN,



2017 to the current level of 28.0%.

A survey of maize flour samples from different regions in Tanzania gave mixed results with 80.0% of the samples being compliant for iron while 20.0% and 40.0% were complaint for folic acid and zinc respectively (Kiwango, Chacha, & Raymond, 2020). This variation in compliance was also observed in the current study with the B vitamins being more compliant compared to the minerals and vitamin A. This could be an indication of the incorrect premix composition used in the fortification process given that it is delivered as a package and one would have expected a similar trend in compliance for the different components.

Maize is the main staple in Eastern and Southern Africa with the highest per capita consumption worldwide and hence fortification of maize meal would benefit the majority of the population (Galani, Orfila, & Gong, 2020). However, from the low fortification compliance levels to fortification standards reported in most African countries, this objective may not be achieved. This trend could be replicated here in Kenya given that low compliance to fortification standards has been observed (Khamila et al., 2020; MOH, 2017).

Post-implementation studies in South Africa established low levels of fortificants in maize meals (Yusufali, Sunley, de Hoop, & Panagides, 2012). A study conducted in Uganda (SPRING, 2018), observed that fortification was still a challenge in the country despite having mandatory maize flour fortification regulations governing the large millers. In Kenya, low compliance levels have also been observed despite having regulations governing food fortification (Khamila et al., 2020;

MOH, 2017). The low levels of compliance are also an indication of irregular or inconsistent compliance monitoring by the regulatory agencies (Rowe, 2020). This will ultimately lead to a lack of the desired change in the levels of micronutrient deficiencies amongst the population. From the foregoing results across the African continent, compliance to fortification standards remains a major gap and over 1.1 billion expected to benefit from the process could be losing out on this innovation meant to curb micronutrient deficiencies (Worldbank, 2019). This is an indication that regulation without enforcement, would not lead to the desired outcomes hence the need for enforcement by the concerned authorities.

Insufficient data to demonstrate the effectiveness of fortification and the need for good monitoring systems, are key issues that need to be addressed in developing countries with regards to fortification (Osendarp et al., 2018). This, therefore, calls for continuous monitoring to ensure the effectiveness of the fortification process from the factory to households with regard to the stability of the fortified products (Mkambula et al., 2020). Monitoring of compliance is an integral part of the fortification program (Luthringer et al., 2015). However routine monitoring for compliance remains a gap as evidenced by lack of enough data to demonstrate a trend in compliance levels.

Barriers to successful fortification need to be identified and dismantled for the full benefit of fortification to be realized in the country. All the stakeholders involved in food fortification should be brought on board for a discussion on the way forward in improving compliance is given that a lot of investments have been done by the government, development partners and the industry yet the compliance levels are still low (Van Jaarsveld, Faber, & Van Stuijvenberg, 2015). However, there is a need for the Government to continuously monitor the compliance of fortified foods to the set standards. This will be important an important strategy for the food fortification program implementation and informing of policy reviews. Moreover, the frequency of field monitoring for fortified foods needs to be increased and enforcement agencies are tasked to play their role so as



to assure the consumers of adequately fortified foods (Mkambula et al., 2020). This will ensure that the desired long-term goal of reducing micronutrient deficiencies is achieved.

4.0 CONCLUSION

About 14% of the maize meal samples were observed to be contaminated with high levels of aflatoxin above the recommended limit of 10ppb, an indication of less stringent measures in the handling of the grains. These cannot, therefore, guarantee the consumers on the safety of the maize meal in the market. More work still needs to be done by all the stakeholders in the maize industry so as to eliminate aflatoxin contamination and guarantee the population of safe maize meal products. Compliance with food fortification standards is still low at 28% despite all the efforts put by both government and its partners. There is a need for concerted efforts to understand the main causes of the low compliance levels in order to develop targeted strategies for mitigation. This should include further analysis of all the possible barriers to effective fortification process including an understanding of the industries processes and an analysis of the quality of premix used in the exercise.

5.0 ACKNOWLEDGEMENTS

The authors appreciate the European Union for the financial support for this study. All the Public Health Officers, laboratory staff from Jomo Kenyatta University of Agriculture and Technology and the National Public Health laboratory are appreciated for the support offered in sample preparation and analysis.

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