LEVEL OF COMPLIANCE TO QUALITY ASSURANCE AND QUALITY CONTROL PROCEDURES AMONG FORTIFIED WHEAT FLOUR MANUFACTURERS OF DAR ES SALAAM.

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By

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A Dissertation Submitted in (Partial) Fulfilment of the Requirements for the Degree of Master of Public Health of

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CERTIFICATION

The undersigned, certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences, a dissertation entitled "***Level of compliance to quality assurance and quality control procedures among fortified wheat flour manufacturers of Dar es Salaam*****"** in fulfillment of the requirements for the degree of Master of Public Health (MPH) of Muhimbili University of Health and Allied Sciences.

_____

Dr. Jane Mlimbila
(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I **Jacqueline Rwegalulira,** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: _____ Date_____

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DEDICATION

I dedicate this Dissertation to my lovely husband Valence John Mtongole and our beloved children Herieth, Evan and Ethan for their encouragement and tolerance during my studies.

ABSTRACT

Background information: Quality assurance and quality control procedures for food fortification were introduced in fortified wheat flour industries. This was done so as to ensure that the wheat flour circulating in the market are adequately fortified. Adherence to the stipulated quality assurance and quality control procedures helps manufacturer to be able to monitor the products quality and safety before entering the market. Hence it is important to know at what extent are they implement the stipulated procedures and the perceived barriers they encounter during implementation.

Aim of the study: This study assessed level of compliance to specified quality assurance and quality control procedures among fortified wheat flour manufacturers, determined the extent to which fortified wheat flour comply with the specifications and identified industry barriers that affect attainment of compliance.

Materials and Methods: A descriptive cross-sectional study was conducted in Dar Es Salaam involving 6 fortified wheat flour manufacturers from July to August 2017. Six observational checklist were used to assess the level of compliance to QA/QC procedures performed by manufacturers. A total of 216 samples randomly selected from the market were analysed to determine the extent of compliance to the specification. The obtained data were analysed both qualitatively and quantitatively to get the results. Interview guide with semi structured questions was used to collect data from 6 respondents on perceived barriers.

Results: Proportion of compliance to QA/QC procedures implemented by manufacturers was (33.3%), was mainly predicted by observational checklist from TFDA guideline for external monitoring of fortified wheat flour. All respondents perceived QA/QC procedures was important for compliance to food regulations, however, they face difficulties to comply with stipulated QA/QC procedures because of perceived barriers: competition with non-fortifying or non-compliant producers, Poor laboratory capacity, lack of regulatory monitoring and clarity, awareness and attitude to food fortification and lack of training in the area of food fortification. Only (67.6%) of samples analyzed were adequately fortified.

Conclusions: Two manufacturers (33.3%) out of six complied with stipulated QA/QC procedures stipulated in the manual for internal monitoring of wheat flour. Compliance to Food Fortification Regulations was highly affected by competition with non-fortifying or non-compliance producers, Poor laboratory capacity, lack of regulatory monitoring and enforcement, awareness and attitude to food fortification and lack of training and expertise in the area of food fortification. Percentage of overall inadequately fortified wheat flour was (32.4%).

DEFINITIONS

Compliance means conforming to relevant guidelines, standard, laws and regulations.

Quality control (QC**)** refers to the techniques and assessments used to document compliance of the product with established technical standards, through the use of objective and measurable indicators.

Quality assurance (QA) refers to the implementation of planned and systematic activities necessary to ensure that products or services meet quality standards. The performance of quality assurance can be expressed numerically as the results of quality control exercises.

Micronutrients means essential dietary nutrients including vitamins, minerals or trace elements that are required in very small quantities and are vital to development, disease prevention and wellbeing of human beings.

Internal monitoring refers to the quality control and quality assurance (QC/QA) practices conducted by producers, importers and packers.

External monitoring refers to the inspection and auditing activities carried out at production centers (factories and packers) and importation custom sites. Governmental authorities are responsible for external monitoring, which is implemented as a mechanism to assure compliance with standards and regulations.

Fortification means deliberately increasing the content of essential micronutrients in a food so as to improve the nutritional quality of food and to provide public health benefit with minimal risk to health.

Fortificant means a substance added to food to provide micronutrients but does not include nutraceuticals or foods for Special Dietary Uses.

Fortified food means food that has undergone the process of fortification as per the provisions of these Regulations (TFDC (Food Fortification) Regulations 2011)

Micronutrient deficiency (also known as **hidden hunger**) is a form of under nutrition that occurs when intake or absorption of vitamins and minerals is too low to sustain good health and development in children and normal physical and mental function in adults.

A premix is a mixture of a micronutrient(s) and another ingredient, often the same food that is to be fortified that is added to the food vehicle to improve the distribution of the micronutrient mix within the food matrix and to reduce the separation (segregation) between the food and micronutrient particles.

Certificate of analysis is the guarantee provided by the premix supplier/manufacturer to the customer (flour mill) that the premix meets the concentration specifications set by the customer.

Qualitative test is a test that provides information on the presence or absence of a specific substance or compound without reference to the amount of that compound in the food, for example, the qualitative spot test for iron in flour.

ABBREVIATIONS

ACR-	Acceptable Compliance Range
et al. -	And others people
FAO-	Food and Agriculture Organization
FIFO-	First In-First Out
FDB-	Food and Drug Board
FMA-	Flour Millers Association
GAIN-	Global Alliance for Improved Nutrition
HPLC-	High Performance Liquid Chromatography
IVACG-	International Vitamin A Consultative Group
PMS-	Post marketing Surveillance
QA-	Quality Assurance
QC-	Quality Control
SOPs-	Standard Operating Procedures
TFDA-	Tanzania Food and Drugs Authority
TFDC-	Tanzania Food, Drugs and Cosmetics Act
UNICEF-	United Nations Children's Fund
USAID-	United States Agency for International Development
WHO-	World Health Organization
% -	Percent

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CHAPTER ONE

1.0 Introduction

1.1 Background Information

Hidden hunger, also known as malnutrition, afflicts more than 2 billion individuals, or one in three people, globally (1). Its effects can be devastating, from serious physical disabilities to life-threatening disorders leading to mental impairment, poor health, low productivity and even death. Even mild to moderate deficiencies can affect a person's well-being and development. In addition to affecting human health, hidden hunger can curtail social economic development, particularly in low and middle income countries (1).

Both the density and bioavailability of micronutrients in the diet are important for achieving optimal micronutrient status (2).Therefore, the best way of preventing micronutrient malnutrition is to ensure consumption of balanced diet that is adequate in every nutrient. Unfortunately, this is far from being achievable everywhere since it requires universal access to adequate food and appropriate dietary habits. In 2000, the *World Health Report1* identified iodine, iron, vitamin A and zinc deficiencies as being among the world's most serious health risk factors (3).

Food fortification is considered to be the most cost effective health interventions that exist today addressing micronutrient malnutrition on large scale (4, 5). Food fortification is one of the nutritional interventions which help to prevent nutritional inadequacy in target populations in which a risk of nutrient deficiency is identified. It doesn't require people to change their eating habits, thus the "target" population continues to eat the food chosen as a "vehicle" which, once fortified, becomes a good source of the micronutrient (6).

The Tanzania government has established a National Food Fortification Program which aims at initializing fortification of Maize flour, wheat flour and edible oil produced by large manufacturers. This program direct large scale manufacturer to mandatory fortifies food products. Wheat flour has been selected as one of the food vehicles to be fortified with

micronutrients essential for human being nourishment. Vitamin B_{12}, folate, iron and zinc are added to wheat flour so as to accomplish the needs (7).

Fortification of wheat flour with vitamins and minerals requires the implementation of quality control and quality assurance procedures, in order to ensure that the fortified flour circulating in the market meet regulations requirements. Therefore, wheat flour manufacturers are responsible for complying with the standards and regulations in the country (8).

Table 1: Minimum requirement for fortified wheat flour

Food vehicle	**Nutrient**	**Fortificant compound**	**Specifications**	
			Minimum	**Maximum**
Wheat flour	Iron	Sodium Iron EDTA	30mg/kg	50mg/kg
	Zinc	Zinc Oxide	30mg/kg	50mg/kg
	Vitamin B12	Vitamin B12	0.005mg/kg	0.025mg/kg
	Folate	Folic Acid	1mg/kg	5mg/kg

Source: TFDC (Food Fortification) Regulations, 2011

In order for manufacturers to ensure safety and quality of fortified wheat flour to the public, they are required to conform to TFDA manual for internal monitoring of fortified wheat flour. This manual prescribes different procedures to manufacturers on how to conduct internal monitoring of fortified wheat flour in their area of production.

The purpose of internal monitoring is to identify and remedy irregularities throughout the production and packaging processes, therefore continuous implementation of quality assurance and quality control procedures in milling industries will help to ensure that the wheat flour produced are adequately fortified hence meet specifications stipulated in standard and regulations. However, information on the level of compliance to quality assurance and quality control procedures is limited in Tanzania and the same has been the case in many low-and middle income countries were the proportion of compliance is not quantified. (9).

Therefore this study aims to assess the level of compliance to quality assurance and quality control procedures and perceived barriers among fortified wheat flour manufacturers in Dar es Salaam. Wheat flour manufacturers have been chosen for this study because previous studies show that wheat flour circulating in the market are not adequately fortified and its due to manufacturers failure to adhere to quality assurance and quality control procedures stipulated in the manual.

1.2 Problem statement

Finding of the first Post Marketing Surveillance (PMS) conducted in Tanzania Mainland, reported that only 52 % of the fortified wheat flour complied with fortification standard (10). Second Post Marketing Surveillance (PMS) conducted in Tanzania Mainland, reported that only 54.2 % of the fortified wheat flour complied with fortification standard (11). In another study, the average pass rate of external quality assurance and quality control activities of fortified foods done in 25 countries supported by GAIN was 45%-50% (12). The results indicated a systematic problem with compliance and the main cause of the problem to be manufacturers' failure to implement and continuously apply quality assurance and quality control procedures (10, 11, 12).

QA/QC procedures are necessary in fortified wheat flour industries as it helps to ensure that food products advertised as, or required by law to be, fortified are adequately fortified, meaning compliant with relevant regulations or fortified as claimed (9). Low compliance to QA/QC procedures has been documented in fortified food industries in low-and middle income countries in Africa and Asia which certainly contributing to persistently under fortified foods reaching consumers (9).However in some countries like Philippines, Vietnam and Indonesia compliance to quality assurance and quality control procedures is high (13). The proportion of compliance in those countries with high compliance were quantified unlike those with low compliance, for instance in Philippines compliance level is 60 %(13).

Perceived barriers by manufacturers are poor quality or unsafe inputs, poor processing procedures and expertise, lack of SOPs and documentation, lack of adequate internal laboratory capacity, improper packaging and handling, lack of awareness of standards and purposeful under-fortification, low priority and capacity for enforcement, lack of appropriate internal budget and expertise to fortify by manufacturers and competition with non-fortifying or non-compliant producers (1, 9, 12, 13)

However, in Tanzania there is lack of knowledge on level of compliance to quality assurance and quality control procedures among fortified wheat flour manufacturers. Many studies on assessing the extent of compliance of fortified wheat flour have been done as documented by

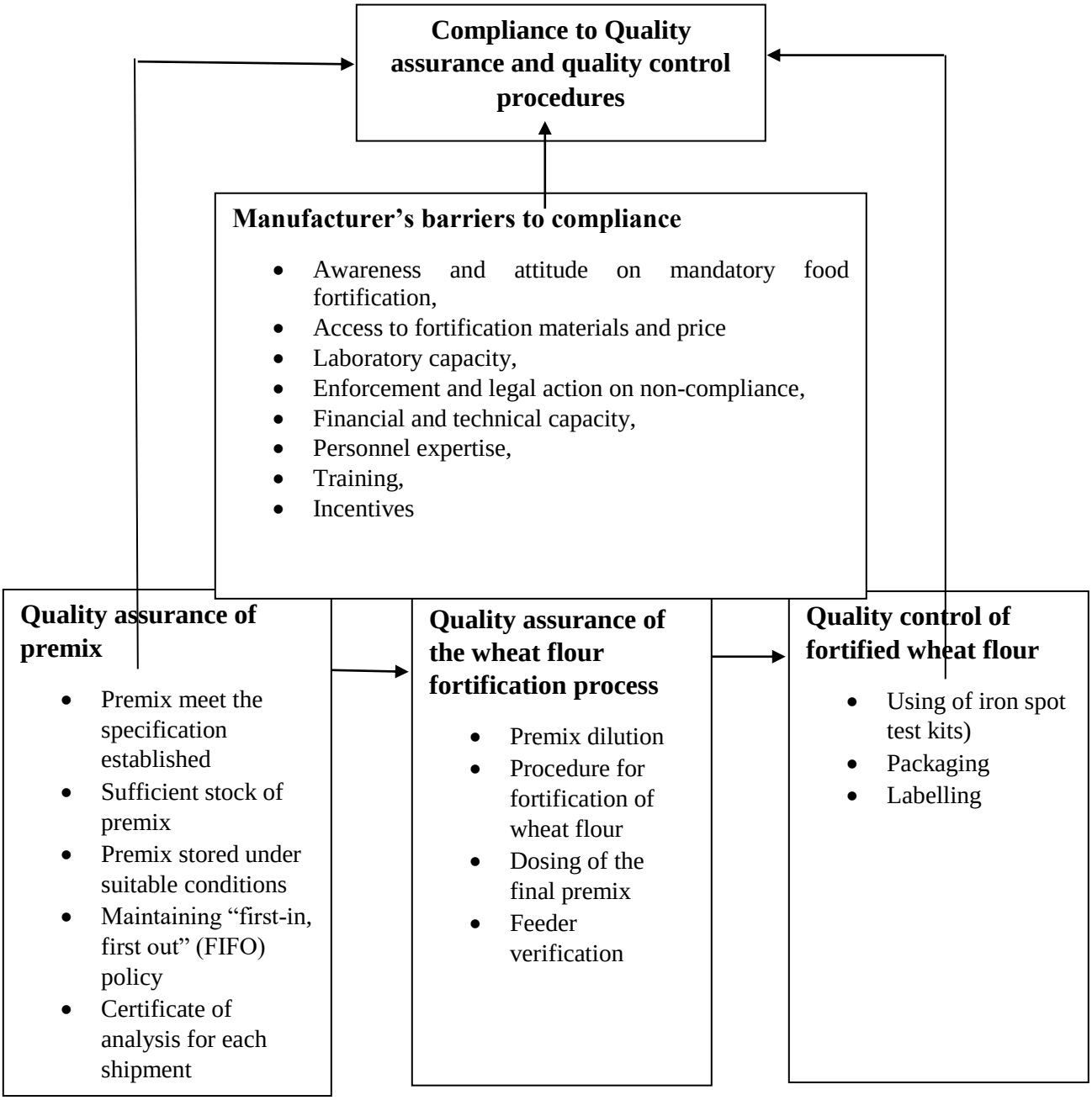
(10, 11, 12), but in the area of assessing level of compliance to quality assurance and quality control procedures among manufacturers and perceived barriers to compliance little is known. This function is left to individual manufacturer's internal policies, which very rarely are made public. Information regarding quality assurance and quality control procedures performed by manufacturers is insufficient and even though some industries have these procedures, but they are not clear. This study aims to fill this knowledge gap in fortified wheat flour industries.

Therefore this research intends to assess level of compliance to fortification quality assurance and quality control procedures and barriers affecting implementation among fortified wheat flour manufacturers**.** Results obtained from this research will be useful to the regulators of these products as well as manufacturers by identify critical points along the fortified wheat flour production that prevent consistent compliance in the market.

1.3 Conceptual framework

This study will be guided by the conceptual framework model in figure 1.1 below. Three main factors inter-relate and affect the manufacturer compliance to wheat flour fortification, namely quality assurance of premix, quality assurance of wheat flour fortification process and quality control of fortified wheat flour.

Figure 1: Conceptual framework



Source: TFDA Guidelines for external monitoring of fortified foods 2013

Also, there are identified barriers in industry level which in one way or another may also contribute to non-compliance. This model, manufacturer's level of compliance to wheat flour fortification is considered excellent when all stages within the specified quality process are adequately followed and implemented. Also, all manufacturers' barriers have to be taken into account since they can act singly and/or collectively to influence the level of compliance hence, have to be minimized or eliminated. At the end level of compliance by manufacturers determine the compliance of fortified wheat flour in the market.

1.4 Rationale of the study

Results obtained from this research will be useful to the regulators of this product since it will identify problems at industry level, hence identify critical points along the fortified wheat flour production that prevent consistent compliance in the market.

The study will provide new insight and add knowledge that can be a vital in put in various policy and decision making processes and to the existing literature for future development.

1.5 Research Questions

To what extent are fortified wheat flour manufacturers comply with specified Quality assurance and Quality control procedures as stipulated in TFDA manual for internal monitoring of fortified wheat flour?

1.5.1 Sub-questions

i. To what extent do fortified wheat flour manufacturers implement the quality assurance and quality control procedures?
ii. Determine the extent to which fortified wheat flour comply with the specifications?
iii. What are the perceived barriers to compliance against food fortification regulations among fortified wheat flour manufacturers?

1.6 Research Objectives

This study will have both broad objective and specific objectives as here under;

1.6.1 Broad Objective

To assess the level of compliance to quality assurance and quality control procedures and perceived barriers among fortified wheat flour manufacturers in Dar es Salaam.

1.6.2 Specific objectives

1. To determine the extent to which quality assurance and quality control procedures are implemented by fortified wheat flour manufacturers.
2. To determine the extent to which fortified wheat flour comply with specification**.**
3. To identify the perceived barriers by manufacturers which prevent compliance to food fortification regulations.

CHAPTER TWO

2.0 Literature review

2.1 Introduction

This chapter shows arguments made by different scholars concerning level of compliance by fortified wheat flour manufacturers. The chapter will thus discuss theoretically and empirically the extent to which specified QA/QC procedures are implemented, perceived barriers and to what extent manufacturers are not fortifying wheat flour.

Food fortification of wheat flour plays an important role as one of the highly cost effective intervention in preventing micronutrient deficiencies worldwide, especially to children under five and women of reproductive age. However, critical gap exists between food fortification legislation and compliance which is affecting the impact (12).

2.2 Quality assurance and quality control procedures

QA/QC procedures are made up of a variety of components and mechanisms, including premix procurement and storage controls, feeder and dossifier installation, feeder calibration, feed rate calculations, process controls (such as check weighing of premix addition), record keeping, and laboratory analysis. It also includes quantitative tests for vitamins and minerals in wheat flour (13).

The aim of quality assurance of premix is to ensure that, the factory has enough supply of premix and are properly labeled, premix meet the specifications established for flour fortification such as the micronutrients levels declared on the label is the same as the one in the certificate of analysis and lastly premix are stored under suitable conditions as described on the label by manufacturer and used on the FIFO basis (8).Adequate quality control of food fortification processes has often been overlooked in the past. If this practice continues it will not be possible to realize the benefits potentiated by food fortification (14).

Many food producers in low-and middle income countries in Africa and Asia lack adequate QA/QC and Good Manufacturing Practice, which certainly contributing to persistently under fortified foods reaching consumers (9).

Vitamin and mineral premix is one of the most significant recurring input costs for large scale food fortification (15). Accessing suppliers, volatile prices for premix, lack of quality assurance and monitoring of delivered product and lack of funds to purchase premix are major factors which affect the procuring of adequate quality premix (15).

QA/QC procedures tend to be better in larger production facilities that have the capacity and resources to establish strong procedures and qualified personnel to undertake them. In Indonesia, approximately 60% of total salt is produced in large-scale facilities that have good process control procedures, laboratories, and qualified laboratory staff. The remaining 40% of salt is produced by small- and medium-scale processors that do not have the laboratory facilities to make regular quantitative measurements of iodine levels in produced salt and often do not have any process checks or controls (13).

The situation is very similar in the Philippines, where internal monitoring systems are strong in large salt factories and all the flour mills, whereas QA/QC procedures are weak or nonexistent in the numerous small- and medium-scale salt production and iodization facilities, which tend to be the primary source of non-iodized or inadequately iodized salt (13).

The Vietnam salt industry is similar to that in Indonesia and the Philippines, with a large number of small and medium producers with limited or no QA/QC procedures. The majority of flour is milled in large mills with good capacity for QA/QC procedures (13)

Shortcoming of many fortification programmes in the past has been due to failure to establish an adequate quality assurance programme. Evaluation of the fortification of sugar with Vitamin A in Guatemala show that only 30% of sample tested were fortified at level within the legal limit (16). A study of Iodine content in iodized salt samples obtained from several plants in India also provided an example of the need for greater control in processing (17).

Also, industry self-reported quality assurance and quality control (QA/QC) results from national fortification programs in 5 countries, representing 2 maize flour, 5 wheat flour, 1 sugar, and 4 vegetable oil programs, estimated that 45% of product samples were adequately fortified per national standards and the remaining 55% were not (9).

2.3 Extent of non-compliance of fortified wheat flour

Knowing the level of non-compliance of wheat flour is essential for assessing impact of food fortification. For effective fortification impact to be attained, it is crucial to ensure that wheat flour consistently supplies adequate amounts of nutrients at the point of consumption to the at-risk groups (18). Extent of compliance of wheat flour varies from one place to another, with high income countries having high compliance compare to low and mid income countries.

The average compliance rate of external quality assurance and quality control activities of staple food fortification done in 25 countries supported by Global Alliance for Improved Nutrition (GAIN) programmes was 45%-50% (12). From household coverage data, available for 10 national salt iodization programs, only average of 50% of households have access to adequately iodized salt (19)

In Nigeria, level of compliance of 17 flour sample was 23.6% and non-compliance level was 76.47%, and only 29.4% were compliant at the 50% acceptable compliance range (ACR) for vitamin A (20). Also, 98% of wheat flour, maize flour, sugar and vegetable oil randomly purchased from retail market, Vitamin A was below mandated level (21)

In-depth survey of fortified food products in Nigeria reported to have a compliance range of 10 to 30% (22). In Ghana, the survey done by Food and Drug Board in 2011, only 23% of wheat flour were adequately fortified and up to date the level of compliance has continue to decrease up to 13% (23)

Low compliance levels in bread flour and maize meal was found in the study done in South Africa (18).The drawn conclusion was that the low compliance was a consequence of insufficient addition of premix at the mills and not due to nutrient stability.

Despite a mandatory law and full industry capacity to fortify in Kazakhstan, only 25-30% of wheat flour sold on the domestic market is fortified (24). Also, in Pakistan only 14% of edible oil available in the market is in compliance with Regulations (24).

In Cambodia, 22.6% of iron fortified fish, contain iron below the standard level, while 11.5% contain excessive amounts of iron, only the remaining 65.9% comply with the standard (25). Also, 87% and 53.6% of the same samples had inadequate nitrogen and salt content according to international regulations set in the Codex standard for fish sauce.

This means a well-designed monitoring system for quality control and assurance purposes needs to be implemented by producers.

Vitamin A was not detected in 34% and 21% of the sugar consumed in rural and urban regions in Honduras respectively, despite mandatory fortification (27).In another survey, surprisingly 80% of flour miller's owners and 50% of retail cooking oil producers was complying with Standards (28). The compliance of flour millers was high because Flour Milling Association (FMA) collects and sends samples on a monthly basis to an independent laboratory in London.

2.4 Manufacturer's barriers to compliance

Across all food vehicles studied (i.e., salt, oil, maize, and wheat flour) and in most countries, quality control of fortification is lacking. Concrete actions are urgently needed to understand what resource, capacity, governance, policy, or other barriers are limiting implementation, to motivate businesses to comply with fortification legislation and to ensure that governments continually monitor and enforce compliance where fortification is mandatory (29)

To achieve compliance, manufacturer's barriers must be taken into consideration. Industrial barriers such as QA/QC procedures and premix/feeder technology can affect food fortification implementation in Africa (2).Also, quality and quantity of premix added, high cost of premix and inadequate packaging were considered as the major factors for low compliance in wheat flour (20).

In Ghana, lowering of premix dosage below specified levels due to consumer's complaint on flour quality and lack of a level of playing field in regard to fortification were identified as the major factors for non-compliance for wheat flour (23). Furthermore, millers say fortification process was hindering the wheat flour production process which causes unacceptability of the product and hence creating financial and market share losses for them.

Lack of enforcement and a perceived impact on price competitiveness by industry were major factors for low compliance in Kazakhstan (24). In Pakistan (Punjab) wheat flour fortification is mandatory but not yet enforced because of barriers which include mills not having capacity to fortify; more than 75% lack equipment, limited access to premix, lack of technical capacity and lack of on-site quality control laboratories (24).

Even where there is mandatory legislation for maize flour fortification, fortification by millers has been lagging due to the lack of or inadequate industry infrastructure, lack of technology for small commercially packaging mills, the absence of premix distribution mechanism and effective Quality Assurance and Quality Control (QAQC) systems (29).

High price of premix and competition with non-fortifying or non-compliant producers were identified as the major barriers that affect fortification compliance (9). 55% of food industries reported that an incentive and penalty had been used to sway their behavior toward compliance against national fortification standards (9).

Fragmented food fortification Laws and not appropriately set into legal frameworks, fortification not prioritized by food safety and quality control practices, lack of willingness to enforce regulations, lack of appropriate internal budget and expertise to fortify by manufacturers were are identified as the major leading factors to poor compliance (12).

Poor quality or unsafe inputs, poor processing procedures and expertise, lack of SOPs and documentation, lack of adequate internal laboratory capacity, improper packaging and handling, lack of awareness of standards and purposeful under-fortification were cited as barriers to ensuring compliance by industries (9).

Low priority and capacity for enforcement, minimal harmonization of standards and legislation, limited funding; limited personnel for legal action, corruption among inspection personnel, poor laboratory capacity and limited training in rapid testing methods were identified as barriers to insuring compliance by the government (9). Hence, can also affect the compliance to food fortification Regulations

Successful food fortification program require at least the following: political will and support and the willingness to legislate or regulate; private-sector involvement; public-sector support; willingness of both sectors to enforce quality assurance programmes; good data on consumption patterns; social acceptability of fortified food, implying no change in organoleptic properties; and minimal change in cost this is based on recent experience and lessons learned (30).

Weak quality assurance systems at the private sector level; ineffective enforcement of any existing fortification regulations at the public sector level; a lack of proper monitoring and evaluation of the programme and the added cost, e.g. to the millers, the added cost is the sum of premix, equipment amortization, labour and quality control these are some of the potential constrain to compliance to food fortification (1).

2.5 Conclusions

Compliance to QA/QC procedures is essential in making sure people consume fortified wheat flour which meets all the regulations requirements. Therefore, it is vital to implement a well-designed monitoring system for quality control and assurance purposes. Fortification standards have to become fully integrated in the industry licensing, registration and production processes to assure adequate fortification (25, 31).

Despite all the findings from different literature reviews, in Tanzania the extent of compliance to quality assurance and quality control procedures as well as perceived barriers are unknown. Hence the findings from this study may differ slightly or be same as other literature review. Either way it very critical to do the research and attains the results.

CHAPTER THREE

3.0 Research methodology

3.1 Introduction

This chapter explains various methodologies that were used in gathering data relevant to the research topic.The methodology includes study area, study design, study population, sample size, sampling technique, Data collection tools and Techniques, Reliability and validity of measurement, variables, ethical consideration, data processing and analysis and limitations.

3.2 Study area

This study was conducted in Dar Es Salaam city, six fortified wheat flour manufacturers participated in the study.

3.3 Study design

The design of this study was descriptive cross-sectional using both qualitative and quantitative approaches.

3.4 Study population

The study population was six fortified wheat flour manufacturers. Furthermore the study included brands of fortified wheat flours circulating in the market from the above six manufacturers.

3.5 Sampling technique for supermarkets and retail shops

Non-probability convenience sampling was used to select the participant supermarkets and retail shops, target brands of fortified wheat flour samples were collected. However effort was made to select samples from all cross-sections of population.

3.6 Sample size

Samples of fortified wheat flour analyzed for presence of Iron was determined using a formula below

$$n=\frac{Z^2P\,(1-P)}{\mathcal{E}^2}$$

n=Sample size

P=Proportional of fortified wheat flour in the market which do not comply with the specification. Proportional for Tanzania was known and it is 50% (11).

Z=Confidence level (Z=1.96 for 95%)

Ɛ= Margin of error 7% (0.07)

n=216

Then 10% was added for non-response rate.

Therefore, the minimum estimated sample size for products was 216 and all were found.

3.7 Inclusion criteria

a. All manufacturing facilities fortifying wheat flour in Dar Es Salaam region
b. Most informed person on the manufacturing facility who knew about food fortification in depth
c. Only brands of fortified wheat flour from manufacturing facilities under the study.

3.8 Sampling technique at the manufacturing facilities

The list of manufacturing facilities fortifying wheat flour in Dar Es Salaam region was obtained from TFDA. Purposive sampling was used in selecting six key informants from each facility whose views are relevant, important and particularly worth obtaining for the research.

3.9 Data collection procedure

3.9.1 Selection and training of research assistants

Two experienced laboratory analysts and two food scientists were recruited as research assistants. They were trained and familiarized with the study objectives and how to collect data using the tools provided. Results of pre-test were used to correct errors in the study tools.

3.9.2 Qualitative data collection tools

i. **Semi Structured in depth interview:** An interview guide was used to collect appropriate information on the barriers to compliance against food fortification regulations from 6 key informants until no new insights were given regarding the perceived barriers, the saturation point was reached. The interview guide was prepared in both English and Kiswahili versions, to ensure that the target key

informants used the convenient language and provide the required data and information in time.

3.9.3 Quantitative data collection tool

ii. **Observation checklist**: The researcher observed various processes undertaken during QA/QC so as to get reliable information. This approach allowed researcher to explore the whole process in depth and note relevant phenomena that portrayed a clear picture of the problem under study. The aspects observed were:-

a) Cleaning and sanitation

Cleaning and sanitation comprised with four sections which were careful observed namely: production area, packaging area, warehouse and staff facilities and toilets. For manufacturer to comply, compliance of three sections out of four in that aspect was compulsory with the condition that staff facilities and toilets must be among the compliance.

b) Personnel

Personnel comprised of three sections which were careful observed namely: hygiene as required in regulations, wearing protective clothing and trained in the task performed. For manufacturer to comply with this aspect, compliance in all three sections was compulsory.

c) Written procedures on QA/QC

Four sections namely receipt and storage of premix, feeder verification, sampling of flour for quality control and iron spot test for flour were careful observed. For manufacturer to comply, compliance of three sections out of four was compulsory.

d) **Micronutrient premix**

Five subsection namely premix inventory is up to date, Certificate of analysis received per lot, premix is stored under adequate conditions, FIFO system is in place and premix is handled well in fortification site were careful observed.For manufacturer to comply with this aspect, compliance in all five subsections was compulsory.

e) Control of flour fortification

Six sections namely records of feeder performance, premix level in feeder adequate during observation, records of flour produced/premix used up to date, flour sample taken for analysis in every shift and corrective action taken when ration of flour produced/premix is not right and iron content is below factory minimum were careful observed. For manufacturer to comply with this aspect, compliance in all six sections was compulsory.

f) Control fortified flour

Eight sections namely; Records for spot test for iron, qualitative method iron, quantitative method, daily composite sample, last 30 sample stored, labelling meet specification, fortified flour stored adequately and FIFO system applied to dispatch were careful observed. For manufacturer to comply with this aspect, compliance in all eight sections was compulsory.

iii Product analysis;

216 samples were collected randomly from the market to verify the presence of indicator micronutrient (Iron) using standardized semi-quantitative methods "ICheckTM IRON".This rapid and simple to use method for quantifying Iron in wheat flour has been proven to give valid result. Sufficient samples of similar size were collected to facilitate analysis, precautions was taken to maintain product integrity. Also, during sampling batch number and manufacture date were considered.Laboratory analysis was conducted by the competent Food Analyst from Tanzania Food and Drugs Authority Laboratory. Full description of the method that was used is attached as Appendix VI. Data collected from samples tested at the laboratory was analyzed using Microsoft Excel spreadsheet program. A variety of statistical techniques such as measure of central tendency, measure of spread of data and standard curves were performed to provide confidence on reliability of results and the correctness of analysis done. The interpretation of laboratory analysis results was based on specific standard requirements for fortified wheat flour.

3.10 Reliability and validity of measurement

Validity and reliability was ensured through scientific method of collecting, analysing and processing data to respondents, the researcher was explicit, unambiguous and less complicated when formulating an interview guide. The English version of the interview guide was used to conduct interviews. Data were collected by competent researchers in Food science and technology so as to avoid/minimize errors at the field. Apart from that each day after data collection, the team had a short briefing meeting to discuss on the challenges of the day and how to mitigate them on the following day.

3.11 Study Variables

Dependent variable

- Compliance of fortified wheat flour manufacturers to quality assurance and quality control procedures

Independent variables

- Cleaning and sanitation
- Personnel
- Written procedures on QA/QC
- Micronutrient premix
- Control of flour fortification
- Control fortified flour

Issues to explore

- Perceived Barriers to compliance

3.12 Data collection at manufacturing facilities

The researcher visited manufacturing facility with a notes taker, key informants were interviewed using interview guide. Key questions and probes regarding perceived barriers to compliance to food fortification regulations were asked to the interviewer. During the interview the all information provided by key informant was noted. The same procedure was

used until no new insights were given regarding the perceived barriers. Also observational checklist was administered in each industry.

3.13 Data processing and Analysis

Data collected was sorted and checked on daily basis to check their completeness and consistence. In case of any missing information or inconsistence, the interviewer went back to the particular study unit to make necessary adjustment.

3.13.1 Qualitative data

Thematic analysis was used to analyze qualitative data collected through in-depth interviews. Collected data in the form of hand written notes were reviewed and organized manually. The information obtained was critically analyzed word by word to identify significant patterns and themes. Sentences that answer research question from each pattern were highlighted. The highlighted sentences were broken into themes and sub themes followed by coding. Repetitions, filler words and hesitations were eliminated during reporting, as they didn't add value to the context. Nonetheless, new patterns and themes identified from the data were added; thus analysis was both deductive and indicative.

3.13.2 Quantitative data

Data from observational checklist were enter in Ms Excel 2007 and analyzed using Statistical Package for Social Sciences (SPSS) version 16. Simple descriptive statistic was performed to obtain frequency tables.

Compliance of wheat flour with fortification regulations was assessed by quantitative testing of added iron content in samples taken from the selling outlets and comparing obtained levels with the levels specified in the food fortification regulations

The flour was considered to compliant if it had $\geq 30 – 50$ mg/kg iron otherwise the wheat flour was considered non-compliant. The samples were further grouped into three groups (inadequately fortified, adequately fortified and over fortified based on their level of compliance "inadequately fortified" had added iron levels < 30 mg/kg, "adequately fortified" had added iron levels $\geq 30 – 50$ mg/kg "over fortified" had added iron levels > 50 mg/kg.

Descriptive statistics such as frequency and percentage was used to summarize and describe data collected. A chi square test was performed to explore the differences of iron concentration in fortified wheat flour among manufacturers. All analyses were carried out with a significance level of 5%. All statistical tests were two sided and a p-value of < 0.05 was considered to be significant.

3.14 Ethical considerations

Ethical clearance for conducting this study was obtained from the Research Ethical Committee of the Muhimbili University of Health and Allied Science. Permission to conduct this study in fortified wheat flour industries was obtained from Ubungo Municipal Council, Ilala Municipal Council and General Manager of each industry. However based on the understanding of the General Managers and nature of these industries they did not sign consent forms rather verbal consent was used. This study considered all measures to secure the actual permission. Informed consent from the participants were obtained and the interests of all those involved in the study and information provided by each individual or entity remained confidential.

3.15 Pre testing of the data collection tool

Pre testing of the data collection tool (Observational checklist, ICheck^{TM} IRON and English version of interview guide) were done prior the study, at the wheat flour industry located in Kibaha, Pwani region. Four respondents were interviewed and the exercise involved the recruited research assistants as part of practical training to give them experience of all the necessary field procedures. Results of pre-test were used to correct errors in the study tools.

CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

This chapter presents, discusses and analyses the findings of the study. The main objective of this study was to assess the level of compliance to quality assurance and quality control procedures and perceived barriers among fortified wheat flour manufacturers in Dar Es Salaam. It also sought to determine the extent to which quality assurance and quality control are implemented by fortified wheat manufacturers, identify the perceived barriers by manufacturers which prevent compliance to food fortification regulations and determine the extent to which fortified wheat flour comply with the specifications.

4.2 The extent to which quality assurance and quality control procedures are implemented by Fortified wheat flour manufacturers

Six observational checklists were administered to determine the extent to which quality assurance and quality control procedures are implemented by fortified wheat flour manufacturers. This approach allowed the researcher to explore the whole process in depth and note relevant phenomena that portrayed a clear picture of the problem under study. A total of 30 items listed in observation checklist were observed. Each item was given a score of 1 if the observation was in compliance with the requirement and 0 if otherwise. All the items were grouped into six major categories namely cleaning and sanitation, personnel hygiene and availability of written procedures on QA/QC. Others were control of premix, flour fortification process as well as control of the fortified flour. Results on observed group items are presented in Table 2.

Table 2**: Results of the extent to which quality assurance and quality control procedures are implemented by fortified wheat flour manufacturers**

Variable	**Status**	
	Complied N (%)	**Not complied N (%)**
Cleaning and sanitation	6 (100%)	0 (0%)
Personnel	5 (83.3%)	1 (16.7%)
Written procedures on QA/QC	2 (33.3%)	4 (66.7%)
Micronutrient premix	6 (100%)	0 (0%)
Control of flour fortification	4 (66.7%)	2 (33.3%)
Control of fortified flour	0 (0%)	6 (100%)
Overall compliance	2(33.3%)	4 (67.7%)

Overall result show that only two manufactures (33.3%) complied with the quality assurance/quality control requirements for large scale wheat flour. Cleaning and sanitation as well as micronutrient premix were the categories with the highest compliance rate in which all six manufacturers (100%) complied with. In addition, the result shows that none of the manufacturer complied with the criteria on control of fortified flour. Compliance for the case of other aspects was personnel 83.3% (5 out of 6), written procedures on QA/QC 33.3% (2 out of 6) and control over flour fortification process 66.7% (4 out of 6).

4.3 Compliance of wheat flour with specification

4.3.1 Concentration of Iron in the fortified wheat flour

Table 3 presents iron content in wheat flour for manufacturer A, B, C and D while the status on iron content in the flour is indicated in figure 3.

Table 3: Results of t-test on Mean iron (NaFeEDTA) content in wheat flour across manufacturers

Manufacturer	N	Iron (NaFeEDTA) levels in mg/kg			P value
		Min	Max	Mean ± SD	
Manufacturer A	54	24.20	46.20	35.41 ± 6.34	< 0.001
Manufacturer B	54	29.60	53.60	37.43 ± 7.91	
Manufacturer C	55	14.80	52.90	31.44 ± 8.65	
Manufacturer D	53	27.50	54.60	36.17 ± 6.45	
Pooled Sample	**216**	**14.80**	**54.60**	**35.09 ± 7.70**	

4.3.2 Adequacy of Iron in fortified wheat flour

Further assessment on compliance with fortification requirements were performed to show what percentage of wheat flour from each manufacturer was adequately fortified. Fortification quality of wheat flour as compared to national standards varied greatly depending on the manufacturer (Figure 2).

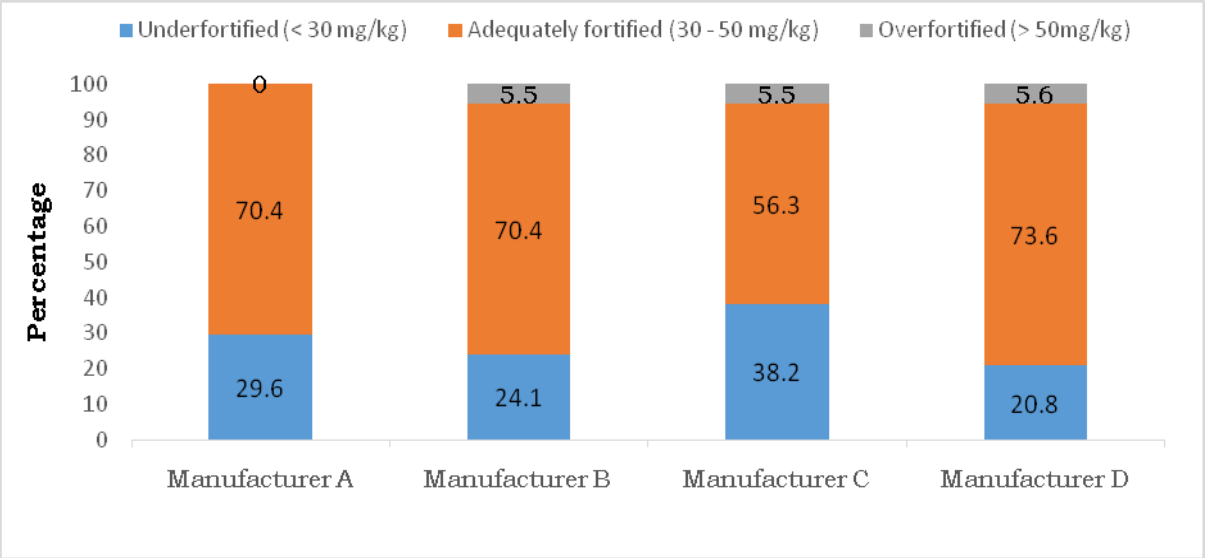


Figure 2: Fortification quality of wheat flour compared to national specification

4.3.3 Compliance of wheat flour as compared to national standards

Also compliance of wheat flour with fortification standards were assessed as depicted in Figure 3. From this figure it is observed that the overall compliance of wheat flour is 67.6%. No significant difference in terms of percentage compliance was observed across the manufactures ($P > 0.05$).

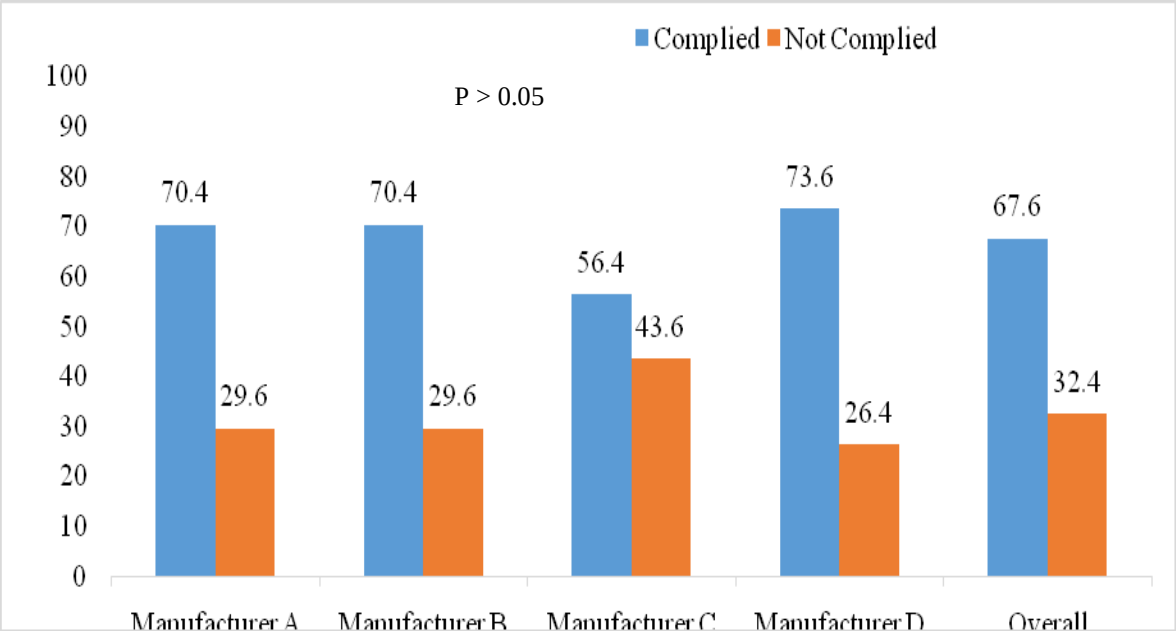


Figure 3: Percentage compliance of wheat flour among manufacturers

4.4 Perceived barriers by manufacturers which prevent compliance to food fortification regulations

4.4.1 Demographic details

In this study a total of six (6) key informants were interviewed through in depth interviews conducted to help identify the perceived barriers by manufacturers which prevent compliance to food fortification regulations. In order to ascertain the validity and reliability of data, basic background information about respondents was crucial. The six respondents were aged between 29-49 years of age. Among six respondents only one was a woman. Four respondents were production managers, two were quality assurance managers, and all were at least Bachelor degree holders in related field. Education levels determine position and ability to analyze issues

Throughout the in depth interviews, respondents identifies barriers they encountered during compliance to quality assurance and quality control procedures/Food Fortification Regulations. Described in this subsection are the themes identified in the respondent's interviews.

4.4.2 Perceived barrier emanated from this interview were

4.4.2.1 Competition with non-fortifying or non-compliance producers barrier

Majority of respondents identify competition with non-fortifying or non-compliance producers as one of the barriers encountered during compliance to quality assurance and quality control procedures/Food Fortification Regulations. A good number of respondents reported that, some wheat flour circulating in the market are not fortified but on the label contain fortification label and declared as fortified to deceive the customers and enforcers. A few respondents show there concerned regarding the price of fortified food being the similar to non-fortified wheat flour. This is supported by

> *"….at the moment, fortified foods on the market has the same price like non-fortified foods and bad enough consumers reach more for those that are not fortified. It is indeed a problem; a producer cannot keep producing fortified foods to comply with the regulations, while in other hand still compete with all other foods that are not fortified."(R#3)*

A good number of respondents reported the reason for some of the manufacturer's intentionally not fortifying wheat flour was to reduce production costs due to price of premix. This is an implication that some wheat flour circulating in the market claimed to be fortified are not and continued to deceive the consumers and enforcers.

A good number of respondents accepted food fortification as mandatory, but urged the government to improve its enforcement and make sure that all wheat flour circulating in the market are adequately fortified as per regulations. As explained by

> *"……..For food fortification to succeed, all wheat flour whether imported or locally produced should be adequately fortified."(R#5)*

4.3.3 Laboratory capacity barrier

4.4.2.2 Laboratory capacity

Ensuring the quality of fortified wheat flour was a common obstacle experienced by manufacturers, majority of respondents reported. A good number of respondents reported doing quality assurance of fortified wheat flour qualitatively using iron spot test kit and the few were not doing any quality assurance. Despite the above, all respondents reported that, their laboratories were poorly equipped to analyze the vitamin and mineral content and some lacked even qualified analysts. One respondent explained

> *"……we are doing what we can, but the fact still remain, most laboratories lack equipment and training to guarantee the quality assurance and control of fortified wheat flour."(R#2)*

Majority of respondents indicated that inadequate internal laboratory capacity in most industries is caused by manufacturer failure to recognize quality assurance and quality control procedures are the backbone of product compliance. A good number of respondents indicated that quality control of fortified wheat flour supposed to be undertaken by external laboratories after every two months were impractical; this is because the cost of analyzing one product was too expensive. This was supported by

> *"…….it costs around 300 $ to analyze one sample of fortified wheat flour, it is unrealistic."(R#3)*

This is an implication that manufacturers are not adequately implementing QA/QC procedures of the fortified wheat flour.

Majority of respondents emphasized on improving quality assurance and quality control measures at industry level. Importance of an adequately resourced laboratory was emphasized by majority of respondents. A good number of respondents indicated a need for industries to invest on equipment and inputs for laboratories. However, few respondents indicated a need for ongoing training on their staff to enhance their expertise in all area of laboratory.

4.4.2.3 Regulatory monitoring and enforcement barrier

Lack of regulatory monitoring and clarity was reported by majority of respondents as one of the barriers to compliance. A good number of respondents identified the need for clear regulations as a top priority for fortification compliance.

In relation to government regulations, inspection and enforcement procedures, the findings of the study depict that majority of respondents emphasized that strong and consistent enforcement play a major role for industries to comply with Food fortification Regulations. However, few, respondents differed with other respondents and they argued that compliance to Regulations is responsibility of each industry regardless of government enforcement capacity as explained by one of the respondent

> *"……With or without government enforcement, it is our responsibility to make sure we comply with the Regulations, No one has to put the gun on our head in order to comply. We have to improve and do more".R#6*

The result provides an insight that majority of the respondents believe that for food fortification program to attain anticipated goals, effective regulatory monitoring is necessary.

Regarding enforcement capacity by regulatory authorities, it was pointed out by a good number of respondents that it is still very poor and it needs improvements especially in hard to reach areas of the country as pointed out by one of the respondent, However few respondents expressed a high level of trust in enforcement capacity.

> *"…….The responsible authorities should take caution when regulating these fortified products found in all parts of the country, because some manufacturers are very clever are taking some of non-fortified products in hard to reach areas"(R#1)*

A good number of respondents were able to point out their views on the reasons that could be linked with weak enforcement of fortification regulations. Majority of respondents were of the opinion that limited resources such as funding and personnel are the major causes of weak enforcement capacity and that regulatory authorities do not give high priority on issues related

to enforcement of food fortification regulation especially when there as other competing food safety issues as pointed out by one of the respondent.

> *"…High priorities are given in the area of food safety, but when it comes to nutritional intervention such as food fortification less effort is displayed by the government, this apply even in terms of funding allocation".(R#5)*

As a means to rectify the situation, majority of respondents prioritized human and financial resources from the government, as they believed that compliance at the industry level would improve with greater monitoring frequency. This implied that allocation of adequate resources is very important for effective enforcement.

In addition, failure to take legal action to non-fortifying industries by responsible authorities was pointed out by a good number of respondents as one of the weaknesses as far as enforcement of fortification regulation is concerned. Majority of respondents believed severe legal action such as license suspension and factory closure to be particularly effective hence suggested to be widely used. This is an implied that current penalties are not severe enough to encourage compliance to fortification regulations.

As a means to rectify the situation, it was suggested by the majority of respondents that, regulatory authorities should put more effort on enforcing the regulations and give severe punishments to violators as one of the respondent proposed,

> *"……..We have been fortifying for five years, I think it is time for the responsible authorities to start taking legal action against industries which are not fortifying, no more excuses. Also penalties have to be more severe".R#6*

Regarding the scope of the current food fortification regulations, the findings of this study show that a good number of respondents were not happy on exclusion of small and medium scale processors and were of the views that there is a need for the current Food Fortification Regulation to be reviewed, so that it can incorporate all manufacturers of wheat flour, maize

flour and edible oil regardless of their scale of production as reported by one of the respondent.

> *"…….it is time for all manufacturers, large scale, medium scale and small scale to start fortifying and the current Regulations have to be reviewed as soon as possible and include everyone. For sure this will bring fairness and effectiveness."R#4*

A good number of respondents illustrate the need for mandatory legislation and enforcement to level the playing field and placed high importance on improving clarity of regulations. However, few respondents emphasized that legislation, regulations and enforcement regimes should be improved to ensure clear and consistent mechanisms are in place and to raise overall compliance of fortified wheat flour which is still low. This is supported

> *"…….we needs regulatory monitoring that can sufficiently identify and hold producers accountable for under-fortified products."R#2*

However few respondents believed the use of Incentives such as subsidies for inputs and equipment, could improve effectiveness in encouraging compliance with mandatory fortification. As one respondent explain

> *".....Regulations on paper will not improve fortification compliance without real incentives as well as strong consequences which drive non-fortified foods out of market."R#4*

4.4.2.4 Awareness and attitude to food fortification

Majority of respondents reported that, awareness and attitude of both manufacturers and consumers to food fortification affected compliance to food fortification regulations.

Although majority of respondents knew the reason for doing food fortification, few respondents were unable to clearly mention all vitamin and minerals which are mandatory required to be added in wheat flour. This is an implication that they don't know exactly which micronutrients need to be added in wheat flour as one respondent reported

"……..I just fortifies wheat flour because I was told to. I don't know exactly what vitamins and minerals are added. I just add the specified addition ratio."R#5

A few respondents reported, high mistrust by distributors in relation to their motivation to fortify wheat flour, some distributors were concerned that flour fortification might cause taste changes and obesity. Hence they implied a need to promote advocacy and communications on food fortification.

".....once we have campaigns on the importance of consuming fortified foods, the consumers and distributors would be able to understand the advantage they are missing and will start to demand fortified products."(R#2)

"……communication is one of the means if succeed will rapidly increase consumers and distributors awareness (R#5)

This result, provide an insight that if food fortification is not well promoted to the consumers, may lead to the belief that vitamins and minerals added are harmful.

A range of communication channels were mentioned as the preferred method of disseminating flour fortification information to the public. Majority of respondents were quick to suggest mass media, such as television, posters, banners and radio advertising. However, potentially a better technique, and one endorsed by few respondents, was to inform consumers at the point of sale.

Majority of respondents indicated that, the government was most trusted for dissemination of flour fortification information to the public. However, few respondents indicated it was the responsibility of each manufacturer to disseminate the information.

Majority of respondents suggested that messages should be the same for the whole population. Few respondents suggested that the message should be short, simple, comprehensive and understandable to everyone.

"……..The message should be very simple, short and understandable." R#5

4.4.2.5 Training and expertise in the area of food fortification

Majority of respondents explained lack of trained personnel is one of the barriers that still exist in several industries. They implied training helps personnel with better understanding of QA/QC procedures involved during fortification.

"…..only someone trained in area of QA/QC procedures can effectively implement the fortification process." R#4

Few respondents indicated they needed technical support from the government for effective implementation and monitoring of wheat flour fortification. However, a major concern of the majority of respondents was the sustainability of the food fortification program, because was donor dependent. This is an implication that, the government should continue to provide training and provide technical support to the manufacturers in the area of food fortification.

CHAPTER FIVE

5.0 Discussion

5.1 Introduction

The main objective of the study was to assess the level of compliance to quality assurance and quality control procedures and perceived barriers among fortified wheat flour manufacturers in Dar es Salaam. The results indicate that, compliance to QA/QC procedures by manufactures is inevitable in order for the fortified wheat flour to comply with regulatory specifications. From the data collected from the field it was revealed that, majority of manufactures are aware of mandatory food fortification and the respondents understand the benefit of doing fortification to the wheat flour. Despite understanding the importance of doing food fortification, still most of them were not complying with QA/QC procedures as stipulated in the manual for internal monitoring of fortified wheat flour. This was well indicated, through the results of the observation checklist performed in each industry. Failure to properly comply with QA/QC procedures has resulted to non-compliance of fortified wheat flour in the market by 32.4%.

5.2 Extent to which quality assurance and quality control procedures are implemented

Results from this study, revealed only two (33%) manufacturers complied with the stipulated QA/QC procedures and the remained four (67%) failed to comply as depicted in (**Table 2**). These findings give an insight that the probability of millers not meeting uniform fortification is very high and therefore jeopardize the quality of fortified wheat flour.

The extent to which quality assurance and quality control are implemented can be supported by other findings. Food producers in low-and middle income countries in Africa and Asia lack adequate QA/QC and GMP, which certainly contributing to persistently under fortified foods reaching consumers as reported by (9).

But contrary to the findings of this study, (13) reported that in Indonesia, Philippines and Vietnam approximately 60% of total salt and wheat flour are produced in large-scale facilities that have good process control procedures, laboratories, and qualified laboratory staff. It is reported that QA/QC procedures tend to be better in larger production facilities that have the

capacity and resources to establish strong procedures and qualified personnel to undertake them (13). Further investigation need to be undertaken to explore the reasons associated with low adherence to QA/QC procedure so that appropriate intervention is undertaken.

5.3 Compliance of wheat flour with specification

The results presented in this study suggest that the majority of the millers attempt to fortify, as seen from the fact that no sample in which no added iron was detected (**Table 3**). However, the amount of iron added in the wheat flour was not consistent and in most cases it was below the required amount (**Figure 2**). It was observed that the overall compliance of wheat flour was 67.6%. (**Figure 3**). Based on the fact that in Tanzania fortification is mandatory for wheat flour, one would expect compliance to be more than 90%. This implies that wheat flour industries are currently not guarantee provision of wheat flour with adequate iron concentration to the population. This has a negative implication on the attainment of projected impact of mandatory Tanzanian food fortification programme.

The overall compliance rate reported in this study is comparable with data documented from Cambodia (25). However, the same results disagree with the findings reported by (12, 20, 24). One of the reason for low compliance could be failure by manufacturers to adequately implement QA/QC procedures, this can be supported by other findings reported by (9, 10, 11).

Nevertheless, failure by manufacturers to adequately implement QA/QC procedures could be because of the perceived barriers identified by manufacturers which were competition with non-fortifying or non-compliance producers, Poor laboratory capacity, lack of regulatory monitoring and enforcement awareness and attitude to food fortification and lack of training and expertise in area of food fortification

5.4 Perceived barriers by manufacturers during compliance to QA/QC procedures/Food Fortification Regulations

Results from this study identified five barriers mostly dominated the list of themes perceived by industries. These barriers were competition with non-fortifying or non-compliance producers, Poor laboratory capacity, lack of regulatory monitoring and enforcement

awareness and attitude to food fortification and lack of training and expertise in the area of food fortification, were identified by majority of respondents (**Figure 2**).

The findings regarding perceived barriers by industries reported in our study are comparable with the findings reported by different authors across the world 23, 24, 31, 32, 33). Contrary to previous findings (14, 26), our findings did not observe the quality and quantity of premix added, high cost of premix and inadequate packaging as the major barriers for low compliance in wheat flour.

In many regulatory monitoring systems, budget constraints lead to insufficient resources devoted to fortification regulation, often because of competing priorities. Low enforcement and compliance result largely from a lack of resources or an unwillingness to detect under fortified foods and hold industry accountable. Without strong political willingness to enforce, justifying investments in resources for enforcement is difficult.

Respondents reveal that many countries lack adequate laboratory capacity, including equipment, supplies, and trained personnel. Sampling quantity and data quality are likely to reflect the quality of technical and human resources available within laboratories. Fortified and non-fortified products are virtually identical and without the use of some form of analytical equipment, manufactures have little indication as to whether vitamins and minerals have been added in the declared amounts or will perform as claimed.

Food laws, regulations, and standards related to mandatory fortification are often disjointed and do not clearly present the roles of stakeholders or the range of enforcement mechanisms that can be used legally. One of the most critical themes drawn from this study's findings, from the perspective of industry, is that strong and consistent enforcement play a major role for industries to comply with Food fortification Regulations. At the root of inadequately fortified products is poor regulatory monitoring and enforcement that lead to non-compliance among industries (44, 45)

Attitudes toward established food safety laws and compliance with them has been explored previously; parallels can be drawn to similar issues of food fortification (44, 43)

5.5 Study limitations

This study is not without limitations that must be considered

i. Selection bias may have been introduced since respondents may have been better informed or may consider fortification efforts more important than non-respondents.

ii. The sample size was relatively small thus, this study intended to summarize perspectives and experiences from qualitative point of view while providing an inference that QA/QC procedures implemented by industries need improvement.

CHAPTER SIX

6.0 Conclusion and Recommendations

6.1 Introduction

The goal of any wheat flour manufacturer should be to provide fortified wheat flour that meets specifications stipulated in Food Fortification Regulations. QA/QC procedures implemented by industries play a critical role in the safety and quality of final products. Moreover, for industries which do not adequately implement the stipulated QA/QC procedures, the potential for wheat flour to be inadequately fortified is even greater. In view of the findings of this study the following conclusions can be made:

6.2 Conclusions

Although progress on national food fortification is impressive, the results are still fragile. The findings from this study show that there are several weaknesses undermining the effectiveness and sustainability of current fortification efforts. The levels of added iron in wheat flour are unsatisfactory across all manufacturers and far from being compliant with the prescribed National Wheat Flour Fortification specifications. It is suggested that this may very likely be due to low adherence to the QA/QC procedures for fortified wheat flour at the industry level due to technological and other barriers that industry face on implementation of the fortification standards. It is also an indicative of inadequate or ineffective monitoring of compliance by the regulators. Ultimately, the effect is that the addition intake of added iron expected to be provided to the consumer is not realized and this potentially reduces the targeted reduction/or prevention of vitamin and mineral deficiencies expected through fortification programme.

6.3 Recommendations

From the conclusions drawn, it is therefore recommended that:-

a) Wheat flour manufactures should continue to implement quality assurance and quality control procedures stipulated in the manual so as to avoid non-compliance of fortified wheat flour.
b) Law enforcers should focus on strong effective enforcement mechanism that influence compliance with national standards and hold non-compliance industries accountable.

c) The government should allocate enough budgets to ensure sustainability of regulatory monitoring activities in area of food fortification. Prioritize funding for inspection, sample collection, laboratory testing and technology transfer to industries.
d) Manufacturers should invest heavily on equipment and inputs for laboratories and provide ongoing training to their laboratory technician.
e) The government should continue to provide training and technical support to the industries which are fortifying wheat flour.

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Appendix I: Observational checklist with compliance to QA/QC procedures

This checklist is adopted from WHO guideline for monitoring fortified foods and TFDA guideline for conducting external monitoring of fortified foods.

Name of the factory……

Postal address……..

Physical address……..

Tel……..

Fax……..

ASPECTS	**OBSERVATIONS**	
	COMPLIED	**NOT COMPLIED**
1.1 Cleaning and sanitation		
1.1.1 Production area		
1.1.2 Packaging area		
1.1.3 Warehouse		
1.1.4 Staff facilities and toilets		
Sub total		
1.2 Personnel		
1.2.1 Hygiene as required in regulations		
1.2.2 Wearing protective clothing		
1.2.3 trained in the task they perform		
Sub total		
1.3 Written procedures or instructions for:-		
1.3.1 Receipt and storage of premix		
1.3.2 Premix dilution (if applicable)		
1.3.3 Feeder verification		
1.3.4 Sampling of flour for Quality control		
1.3.5 Iron Spot test for flour		
Sub total		
2. Micronutrient premix		
2.1 Premix inventory is up to date		
2.2 Certificate of Analysis is received per lot		
2.3 Premix is stored under adequate conditions		
2.4 “First-in-first-out” system in place		
2.5 Premix is handled well in fortification site		
Sub total		
3. Flour fortification		

3.1 Premix dilution (if applicable)		
3.1.1 Homogeneity assessed		
3.1.2 Adequate storage and handling		
3.2 Records of feeder performance available		
3.3 Premix level in feeder adequate during observation		
3.4 Records of flour produced/premix used up to date		
3.5 Flour sample taken for analysis in every shift		
3.6 Corrective actions taken when:-		
3.6.1 Ratio of flour produced/premix is not right		
3.6.2 Iron content below factory minimum		
Sub total		
4. Fortified flour		
4.1 Records of flour samples analyzed using		
4.1.1 Spot test for iron		
4.1.2 Qualitative methods Iron (External Lab)		
4.1.3 Quantitative method (External lab)		
4.2 Daily composite sample are prepared		
4.3 Last 30 samples are stored and available		
4.4 Labeling meets specification		
4.5 Fortified flour is stored adequately		
4.6 “First-in-first out” system applied to dispatch		
Sub total		
Grand Total		

Appendix II: In depth interviews guide –English version
Start by explaining the ground rules as follows:

Before we start I would like to remind you that there are no right or wrong answers in this discussion. We are interested in knowing what you think, so please feel free to be honest and to share your point of view. It is very important that we hear your opinion.

Questions and some probes

1. What is your role in this manufacturing facility?
2. According to you, what are the reasons for doing food fortification?
3. For how long have you been fortifying wheat flour?
4. What barriers, if any, that you encounter in ensuring compliance to QA/QC procedures/food fortification regulations?
    - Awareness and attitude on mandatory food fortification,
    - Access to fortification materials and price
    - Laboratory capacity,
    - Financial and technical capacity,
    - Personnel expertise,
    - Training,
    - Incentives
    - Others
5. How can these barriers be overcome?

Appendix III: Mwongozo wa usahili –Kiswahili version
Anza kwa maelezo ya masharti ya msingi yakuzingatia:

Kabla ya kuanza, ningependa kukumbusha hakuna jibu sahihi wala jibu lisilosahihi kwenye mahojiano haya.Ningependa kujua maoni yako, hivyo basi jisikie huru kusema ukweli na kutoa maoni yako.

Maswali na dadisi

1. Wazifa wako ni upi kwenye hii kampuni?
2. Kwa maoni yako, kwa nini tunaongeza virutubisho kwenye vyakula?
3. Ni kwa muda gani sasa, umeanza kuongeza virutubishi kwenye unga wa ngano?
4. Ni vikwazo gani unakutana navyo, kwenye kuhakikisha unakidhi utaratibu wa kudhibiti na kukidhi ubora wa uongezaji virutubishi kwa unga wa ngano?
    - Uelewa na mtazamo uongezaji virutubishi kwa lazima
    - Bei na upatikanaji wa virutubishi
    - Uwezo wa maabara,
    - Uwezo wa kifedha na kiufundi,
    - Utaalamu wa wafanyakazi ,
    - Mafunzo,
    - Motisha
    - Mengineyo
5. Jinsi gani tunaweza kushinda vikwazo hivyo?

Appendix IV: Informed Consent – English version

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS.

Introduction:

Greetings! My name is Jacqueline Rwegalulira, a Master of Public Health (MPH) student. I'm working on this research project with the objective of assessing the level of compliance to quality assurance and quality control procedures and perceived barriers among fortified wheat flour manufacturers in Dar es Salaam.

Purpose of the study

The purpose of the interview is to collect information from fortified wheat flour manufacturers on extent to which quality assurance and quality control are implemented by fortified wheat flour manufacturers and identify the perceived barriers by manufacturers which prevent compliance to food fortification regulations in Dar Es Salaam. You are being asked to participate in this study because we believe that you have particular experiences that may be important to the study.

What participation Involves

If you agree to participate in this study you will be required to answer a series of questions through an interview.

Confidentiality and privacy:

I assure you that all the information collected from you will be kept confidential. Only people working in this research study will have access to the information. Your name will not be written on this form, and will never be used in connection with any of the information you tell me. You do not have to answer any questions that you do not want to answer, and you may end this interview at any time you want to.

Duration

The interview should take less than an hour. I will be taping the session because I don't want to miss any of your comments

Benefits

The information you provide will help us and other stakeholders in the national food fortification program and regulatory authorities in the country on issues related to to food regulations.

In case of injury

We do not anticipate any harm to occur to you or your family as a result of participating in this study.

Payment

No payment will be paid to you for participation and vice versa

Whom to contact

If you ever have questions about this study, you should contact

Principal Investigator, Jacqueline Rwegalulira, Muhimbili University of Health and Allied Sciences (MUHAS), P.O. Box 65001, Dar es Salaam. (Tel. No. 0754 890 659)

Supervisor Dr Jane Mlimbila, (MUHAS) P.O. Box 65001, Dar es Salaam. (Tel. No. 0713 210174)

If you have questions about your right as a participant, you may call

Dr. Joyce Masalu, Chairperson of the College Research and Publications Committee, P.O. Box 65001, Dar es Salaam. Tel: 2150302-6

Agreement of the Participant

If you agree to participate in this study, sign below

I …….. Have read and understood the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participants ……..

Signature of research assistant……..

Date of signed consent …….

Appendix V: Informed Consent – Kiswahili version

CHUO CHA SAYANSI NA TIBA MUHIMBILI, KURUGENZI YA TAFITI NA MACHAPISHO

FOMU YA RIDHAA, KUSHIRIKI KWENYE UTAFITI

Ridhaa ya kushiriki katika utafiti

Habari! Jina langu ni Jacqueline Rwegalulira.nafanya kazi katika mradi huu wautafiti wenye lengo la kuangalia kiwango cha kukidhi utaratibu wa kudhibiti na kukidhi ubora wa uongezaji virutubisho kwenye unga wa ngano,na kutambua vikwazo vinavyozuia kukidhi viwango vya uongezaji virutubishi kwenye viwanda, jijini Dar es Salaam.

Lengo la utafiti.

Utafiti huu una lengo la kukusanya taarifa miongoni mwa wazalishaji wa unga wa ngano ulioongezwa virutubisho, kuhusu mambo wanayofanya kukidhi utaratibu wa kudhibiti na kukidhi ubora wa uongezaji virutubisho na pia kutambua vikwazo vinavyozuia kukidhi viwango vya uongezaji virutubishi kwenye viwanda

Ushiriki

Kama utakubali kushiriki kwenye utafiti huu, utapaswa kujibu maswali tofauti kupitia mahojiano

Usiri

Unahakikishiwa kwamba taarifa zote zitakazokusanywa kutoka kwako zitakuwa ni siri,ni watu wanaofanya kazi katika utafiti huu tu ndio wanaweza kuziona taarifa hizi. Hatutaweka jina lako au taarifa yoyote ya utambulisho kwenye kumbukumbu ya taarifa utakazotupatia. Haulazimiki kujibu maswali ambayo hutapenda kuyajibu.Hata hivyo majibu yako sahihi yatatusaidia sana katika utafiti huu.

Muda

Mahojiano hatachukua Zaidi ya saa moja. Nitarekodi mahojiano haya hili niweze kupata maelezo yote muhimu bila kipingamizi.

Faida

Taarifa utakazotupatia zitatusaidia sisi na wadau wengine katika program ya kitaifa ya uongezaji virutubisho na mamlaka za udhibiti wa vyakula katika masuala yanayohusu Ungezaji virutubisho kwenye vyakula.

Madhara

Hatutarajii madhara yoyote kutokea kwako wala kwa familia yako kwa kushiriki katika utafiti huu.

Muda

Hakuna malipo yoyote yatakayotolewa kwa ushiriki wako na wewe pia hutatakiwa kutoa malipo yoyote kwangu.

Watu wakuwasiliana nao

Kama una maswali kuhusu utafiti huu unaweza kuwasiliana na mratibu mkuu wa mradi, Jacqualine Rwegalulira, Chuo kikuu cha Sayansi na Tiba Muhimbili, S.L.P 65001, Dar es salaam (Simu 0754 890 659).

Msimamizi wa utafiti Dkt Jane Mlimbila, Chuo kikuu cha Sayansi na Tiba Muhimbili, S.L.P 65001, Dar es salaam (Simu 0713 210174)

Kama utakuwa na maswali yoyote kuhusu haki zako kama mshiriki unaweza kupiga simu kwa Dr. Joyce Masalu, ambaye ni Mwenyekiti wa kamati ya chuo ya utafiti na machapisho, S. L.P 65001, Dar es salaam.Simu namba: 215030-6

Kama umekubali kushiriki, saini hapo chini

Mimi …….nimesoma/nimeilewa hii fomu, maswahili yangu yamejibiwa. Nakubali kushiriki katika utafiti huu.

Saini ya mshiriki ……

Saini ya mtafiti ……..

Tarehe ya makubaliano ……

Appendix VI: Method for Determination of Iron in Wheat Flour

DETERMINATION OF IRON IN WHEAT FLOUR

ICheckTM IRON

1. **SAMPLE PREPARATION**

   Prepare a solution of your sample by diluting it in water to an expected iron concentration in the measurement range of icheck^{TM} IRON which is**: 1.5-12.0mg/L**. Record the dilution factor [DF]: DF=[x grams of water + y grams of sample]/y grams of sample].

2. **ADDITIVE PREPARATION**

   Using a new thin needle syringe provided, prepare the ADDITIVE vial [with red cap] by injecting 3mL of water into the vial with the powder through the red rubber septum of the vial cap. Shake vigorously until solution is clear.

3. **ACTIVATION OF iEx VIAL**

   Activate iExTM IRON vial just before use. For this hold the ADDITIVE vial upside down and take up 0.2 mL of the solubilized ADDITIVE with a new syringe with thin needle. Then inject it into the new iExTM IRON vial. The syringe can be re-used if cleaned with water afterwards. Vigorously shake iExTM vial for 10 seconds, let it stand upright at room temperature for 5 minutes. The colour of the iExTM IRON vial will turn yellowish.

4. **INJECT THE SAMPLE**

   Using a new syringe without the needle attached take up 0.6mL of the sample and attach the thicker needle. Hold the syringe with the needle pointing up and tap on it with fingers in order to release air bubbles. Adjust the volume of the sample to exactly 0.4 mL by injecting excessive volume into the paper tissue.

5. SHAKE THE VIAL

Inject 0.4ml of your sample into the activated iExTM IRON vial and vigorously shake the vial for 10 seconds. Let the vial stand upright at room temperature for at least 30minutes. Reaction Time varies for different iron source types:

Ferrous sulfate-30minutes

Ferrous fumarate-60minutes

Intrinsic iron [i.e flour]-60minutes

Ferric iron [i.eNaFeEDTA]-from 3hours and longer

6. SAMPLE SEPARATION INTO TWO PHASE

If iEx^{TM} upper phase is turbid or less than 0.8cm high, please centrifuge the vial at a low Speed [approx.300rpm] for 1minutes. Let the vial stand for at least 1 hour until a distinctive phase separation has occurred, if no centrifuge is available.

7. RESULTS

With reference to the icheck^{TM} IRON user manual measurements are conducted. The result is displayed in mg/L. The results are reported in mg/kg by multiplying the icheck^{TM} IRON reading value by the dilution factor.

Results (mg/kg) = icheck^{TM} IRON reading (mg/L) x Dilution factor