

**GOOD MANUFACTURING PRACTICES COMPLIANCE: THE CASE  
OF REGISTERED SMALL SCALE MAIZE MILLING INDUSTRIES IN  
UBUNGO AND KINONDONI DISTRICTS, TANZANIA**

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**Master of Public Health Dissertation  
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School of Public Health and Social Sciences**



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**By**

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**A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the  
Degree of Master of Science in Public Health of  
Muhimbili University of Health and Allied Sciences  
October, 2017**

## **CERTIFICATION**

The undersigned certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled “*Good manufacturing practices compliance: The case of registered small scale maize milling industries in Ubungo and Kinondoni Districts, Tanzania*”, in fulfillment of the requirements for the degree of Public Health of Muhimbili University of Health and Allied Sciences.

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(Supervisor)

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**Date**

**DECLARATION AND COPYRIGHT**

I, **Martina John Lyimo**, declare that this **dissertation** report 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.

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Last but not least, I would like to thank the almighty God for his protection and love that enabled me to complete of this work.

**DEDICATION**

This dissertation is dedicated to my beloved children Ethan and Charity for being patient and torelant for my absence from home that related to this work.

## ABSTRACT

**Background:** Good manufacturing practice requirements were introduced in the food industry following the increase in food borne diseases as well as raise in awareness among consumers on food safety issues. GMP in food industries helps to control potential hazards, if adhered to; maintain the certainty of food products through continuous improvement of quality; as well as have food products comply with Tanzania Bureau of Standards and Codex Alimentarius Commission specifications. Low compliance to GMP in small scale food industries has been documented in developing countries for decades. However, in Tanzania there is paucity of knowledge on GMP compliance in small scale food industries.

**Objectives:** This study intended to determine the proportion of registered small scale maize milling industries and factors that affect compliance to GMP in Ubungo and Kinondoni districts of Dar-es-Salaam, Tanzania.

**Methods:** A cross - sectional descriptive study was conducted among registered small scale maize millers who commercially pack maize flour. The study also included food inspectors from TFDA Eastern Zone Office. Both quantitative and qualitative approaches were used to collect data. A total of 155 millers and 3 food inspectors were recruited for the study. GMP for Food Products Observation Checklist adopted from TFDA (Guidelines for GMP of Food Products, 2013) was used to collect GMP compliance data. Closed and open ended questions, and interview guide were administered to the respondents to gather information on factors that affect GMP compliance. Quantitative data were analysed using Statistical Package for Social Sciences (SPSS) and qualitative data were analysed using thematic analysis method. GMP compliance scale was developed from the TFDA Guidelines above and a total score of 65 was used.

**Results:** About 21.9% of registered small scale maize millers were GMP compliant. Millers who were supervised by TFDA in the past 12 months were 5.54 times more likely to comply with GMP requirements while millers who had primary education and below (69%) were less likely to comply with GMP requirements. Also, millers who rented buildings (93%) were less likely to comply with GMP requirements. Majority (90.9%) of the millers perceived that GMP

was necessary in milling industries however, they reported that it is difficult to implement (70.8%). GMP supervision was found to be affected by lack of financial and human resources.

**Conclusion:** A few registered small scale maize millers of Ubungo and Kinondoni Districts complied with GMP. Low GMP compliance was highly influenced by low level of education among millers, lack of guidance from TFDA and within past 12 months use of rented buildings. Supervision is highly affected by lack of resources, human and financial.

**Recommendations:** Small scale maize millers of Ubungo and Kinondoni Districts should be sensitized to abide by GMP requirements. Furthermore they should be encouraged to shift to industrial areas so as to comply with GMP requirements. Tanzania Food and Drugs Authority should increase the budget for supervision activities and employ sufficient number of food inspectors.

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**LIST OF ABBREVIATIONS**

EFSA	– European Food Safety Authority
EZO	– Eastern Zone Office
FDA	– Food and Drug Administration of United States of America
FFDC	– Federal Food, Drug and Cosmetics
FSMS	– Food Safety Management Systems
GHP	– Good Hygienic Practices
GMP	– Good Manufacturing Practices
HACCP	– Hazard Analysis Critical Control Points
SME	– Small and Medium Enterprises
TBS	– Tanzania Bureau of Standards
TFDA	– Tanzania Food and Drugs Authority
SPSS	– Statistical Package for Social Scientists
ZFDA	– Zanzibar Food and Drugs Authority

### **DEFINITION OF TERMS**

Codex Alimentarius Commission -	Is a subsidiary body of the Food and Agriculture Organization of the United Nations and the World Health Organization which is responsible to develop international food standards.
FSMS -	Systems designed to help food business operators to identify, prevent and reduce food-borne hazards.
GMP Compliance -	Adherence to good manufacturing practices for the purpose of producing safe food for human consumption.
Hazard Analysis Critical Control System -	Scientific and systematic way of enhancing the safety of foods from primary production to final consumption through the identification and evaluation of specific hazards and measures for their control to ensure safety of food.
Manufacture -	A complete cycle of production, from receiving through all stages of subsequent processing, packaging, storage to the dispatch of the finished product.
Processing -	Transformation of raw ingredients into food products, or of food into other forms.
Registered small scale maize millers-	Small scale maize milling industries which have been officially recognized by Tanzania Food and Drugs Authority.
Small scale maize millers -	Group of manufacturers characterized by capital investment of machinery up to 200 million Tshs and up to 49 employees.
TZS 328:2014 -	Tanzania Standard for Maize Flour

## CHAPTER ONE

### 1.0 INTRODUCTION

#### 1.1 Background

Good manufacturing practices (GMP) in food, pharmaceutical and medical devices industries is among of the high priority of concerns to the regulators, communities, processors, wholesalers and retailers worldwide (1,2,3). In food industries, GMP means minimum sanitary and processing requirements for producing safe and wholesome food (3). As per National Guidelines for Good Manufacturing Practices for Food Products, GMP means combination of manufacturing and quality control procedures aimed at ensuring that food products are consistently manufactured to their specifications (6). Worldwide, GMP is been made a mandatory requirement in all food manufacturing industries and its implementation is regulated by regulatory authorities (5).

Historically, GMP was initially applied in pharmaceutical and medical devices industries in the United States of America (USA). Before GMP in the early 20<sup>th</sup> century, there were some legislations governing purity, consistency and efficacy of drugs however they were not successful in ensuring total public health protection. In 1938, US congress passed the Federal Food, Drug and Cosmetic (FFDC) Act which led to formulation of GMP requirements (3). The requirements were put in place so as to ensure that pharmaceutical and medical devices industries comply with standards (3).

Later, GMP was introduced in food industries with the idea of ensuring that food products meet safety and quality standards. Compliance with GMP requirements save as prerequisite for the implementation of Hazard Analysis Critical Control Points (HACCP). Furthermore, increases customer satisfaction and protects them from foodborne illness that would result from contaminated food and improve food keeping quality by extending shelf life, which eventually increase profit margin (6,4,5).



In Tanzania, GMP implementation in food industries is regulated by the Tanzania Food and Drugs Authority (TFDA) under Tanzania Food, Drugs and Cosmetics Act, 2003(7). The act directs TFDA to regulate compliance to quality and safety requirements of all food products in the country. For milling industries, manufacturers are obligated to comply with Maize Flour Specifications. In order to achieve that, compliance with GMP requirements among maize millers is inevitable. In Tanzania, GMP requirements in maize milling industries have been categorized into different domains of requirements: location and building; water; sanitation and staff hygiene; raw materials and quality testing; food equipment and process and records (8).

High compliance to GMP in milling industries can help to control the risk of food borne diseases taking into consideration that maize flour is among of high risk food products due to its vulnerability to fungi and other chemical toxins, which can endanger human health. Despite that maize flour is one of the main foods among Tanzanians, information on the GMP compliance in milling industries is limited in Tanzania. Therefore, this study aimed at assessing the proportion of small scale maize millers who comply with GMP and to find out factors that affect GMP compliance. The study focused on registered millers by TFDA in Ubungo and Kinondoni Districts. Small scale maize manufacturers were chosen for this study because previous studies show that small scale industrial sector is the most vulnerable group to failure to adhere to Food Safety Management Systems (FSMS). Information on GMP compliance in these two districts broadens knowledge on GMP compliance in food industries.

In this study, proportion of registered small scale maize milling industries found to comply with GMP in Ubungo and Kinondoni Districts was low (21.9%). The main determinants of GMP compliance were level education of the millers, guidance from TFDA within the past 12 months and building ownership. GMP requirements were perceived as necessary in maize milling industries by majority of small scale maize millers however, they were perceived difficult to be implemented mainly because of low financial capacity, lack of technical capacity, insufficient space to effect changes, use of cheap labour and rented buildings.

Furthermore, the study found out factors that affect TFDA's GMP supervision in Ubungo and Kinondoni Districts were low financial and human resources.

This dissertation has six chapters. Chapter one includes background information, problem statement, conceptual framework, rationale of the study, research questions and objectives. Chapter two explores the literature that contains information on the issues related to GMP compliance in food industries, factors that affect GMP supervision by regulatory authorities, maize miller's factors associated with GMP implementation and their opinions on GMP requirements. Chapter three describes the methodology that was used. Chapter four contains results of the study, chapter five contains discussion of the results and Chapter six summarizes the conclusions and recommendations.

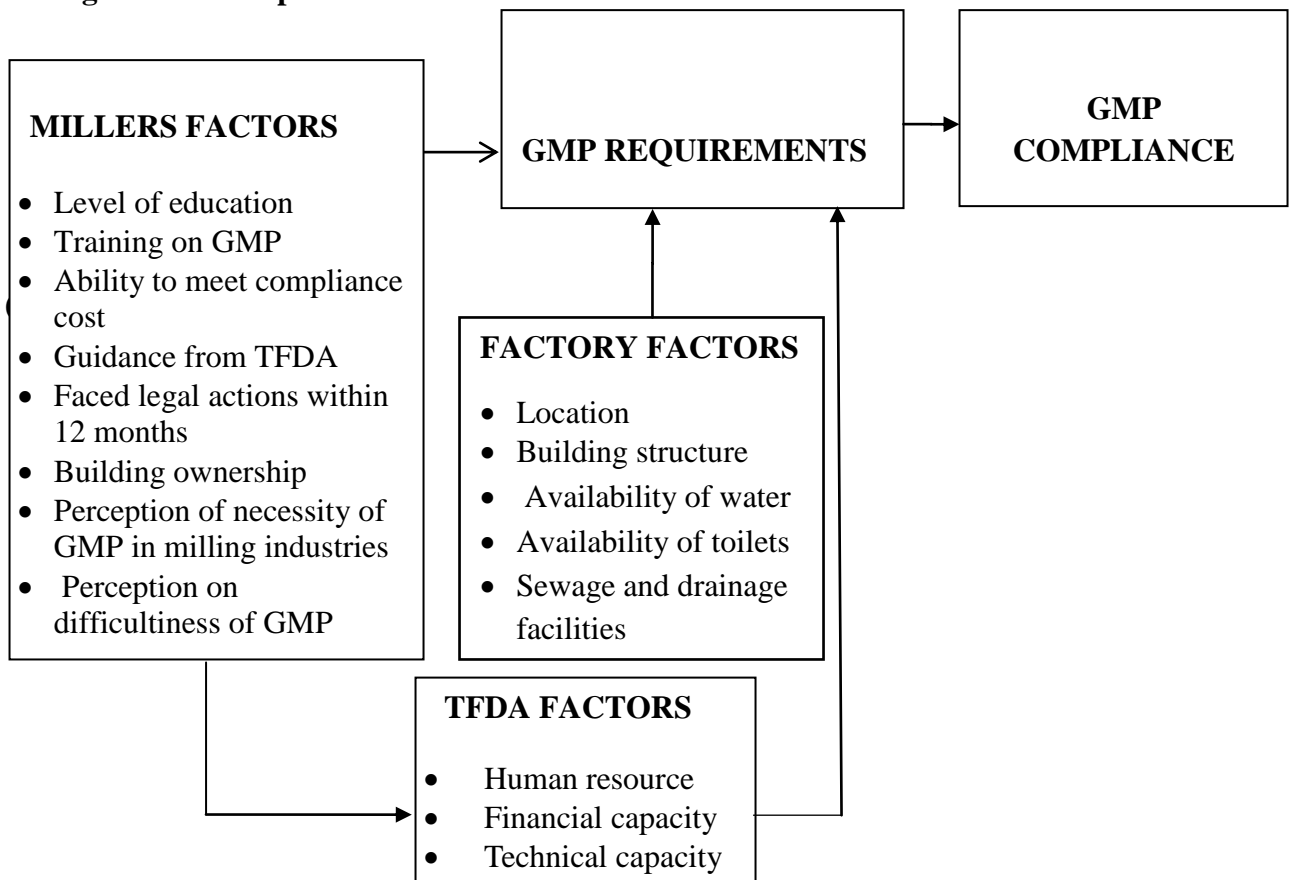
## **1.2 Problem statement**

Low compliance to good manufacturing practices in small scale food industries has been documented in developing countries for decades. For instance, in Kenya, Nigeria and some countries of South East Asia, compliance to GMP requirements is low (9,10,11), although in some few countries like Philippines and Egypt GMP compliance in food industries is high (1). The proportion of small scale food industries adhering to GMP in those countries are not quantified unlike in most of developed countries (12, 13). For example in Poland where the compliance level was found to be 77% (12). In Turkey, poor adherence (92.2%) to GMP has been declared as barrier to trade by food industries managers (13).

Low GMP compliance has been found to be affected by regulatory factors (supply factor) and processors factors (demand factors). On the supply side, these factors are poor regulatory capabilities for supervision caused by high monitoring cost; low financial capacity; lack of enough technical expertise; lack of trained inspectors; multiple government food safety control agencies with unclear boundary of functions of each; inadequate policy and legislation; inappropriate standards; failure to cover the informal sector; limited community involvement and weak law enforcement (14,15). The demand factors are low level of knowledge; high compliance cost; complexity GMP requirements; lack of training; poor management commitment; staff turnover; lack of motivation; inadequate physical conditions of the facility; lack of management skills; and poor working conditions (16,17,18).

However, in Tanzania there is paucity of the extent of knowledge on GMP compliance in small scale food industries. Most of the studies that have been done have assessed GMP knowledge in pharmaceuticals industries. Therefore, this study explored on the proportion of GMP compliance and factors that affect compliance in small scale maize milling industries registered by TFDA in Ubungu and Kinondoni districts. Information on GMP compliance in these two districts broadens knowledge of GMP compliance in food industries. Additionally, factors that affect compliance help to know the causes of compliance.

### 1.3 Figure 1. Conceptual framework



Source: Author, 2017

### Figure 1: Conceptual Framework

Figure 1 presents the conceptualization of the perceived association between extent of GMP compliance and associated factors. Regulatory authorities are required to ensure small scale maize milling factories comply with GMP requirements so that they can produce safe food. However, extent of compliance in maize milling factories depends on the miller's ability to comply with GMP requirements, factory conditions and regulatory authority's capability to regulate them. Ability of millers to comply with GMP requirements is influenced by their level of education, training on GMP, ability to meet compliance cost, guidance from TFDA, building ownership, perception of necessity and difficultness of GMP in milling industries and if they had ever faced legal actions for going against regulatory framework. Regulatory

authority's capability to regulate small scale millers depends on technical capacity, human and financial resources.

#### **1.4 Rationale of the study**

Information on the proportion of GMP compliance and associated factors in registered small scale maize milling industries is crucial to be known because maize flour is among of high risk food products. The findings of this study could help the stakeholders in the milling factories to understand compliance level to GMP and factors associated in registered small scale maize milling industries in Ubungo and Kinondoni Districts. The information could also be used by TFDA in priority setting during planning of educational interventions, inspection and supervision activities in the two districts.

#### **1.5 Research questions**

##### **1.5.1 Main research question**

What is the proportion of registered small scale maize milling industries that comply with GMP and associated factors in Ubungo and Kinondoni districts?

##### **1.5.1 Sub questions**

1. What is the proportion of registered small scale maize milling industries that comply with GMP in Ubungo and Kinondoni districts?
2. What are the registered small scale millers' factors that affect GMP implementation among Ubungo and Kinondoni districts?
3. What are registered small scale millers' opinions on GMP requirements in Ubungo and Kinondoni districts?
4. What are the factors that affect GMP supervision at TFDA in Ubungo and Kinondoni district districts?

**1.6 Broad Objective**

To determine the proportion of registered small scale maize milling industries that comply with GMP and associated factors in Ubungo and Kinondoni districts.

**1.7 Specific Objectives**

1. To determine the the proportion of registered small scale maize milling industries that comply with GMP in Ubungo and Kinondoni districts.
2. To assess registered small scale millers' factors that affect GMP implementation in Ubungo district and Kinondoni districts.
3. To find out registered small scale millers' opinion on GMP requirements in Ubungo and Kinondoni districts.
4. To find out the factors that affect GMP supervision at TFDA in Ubungo and Kinondoni district and Kinondoni districts.

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

#### 2.1 Good Manufacturing Practices compliance in maize milling industries

Good Manufacturing Practices (GMP) compliance in food industries is mandatory in many countries across the continents. In most of the developed countries, it is considered as the prerequisite requirement for HACCP while in developing countries it is considered as satisfactory requirement in food industries. Enforcement of GMP in food industries is controlled by regulatory Authority of a particular country. For instance, in the US, it is enforced by Food and Drugs Administration (FDA), in Europe is enforced by European Food Safety Authority (EFSA) and Zanzibar by Zanzibar Food and Drugs Authority (ZFDA). These agencies are responsible to ensure that industries comply with GMP guidelines/regulations set by the country. However, its implementation and sustainability in food industries require it to be part of food safety laws and regulations of the country and strong management commitment of the processors (25). The principle behind GMP is that a manufacturer is the primary responsible against its implementation, while the regulatory Authority is responsible for monitoring the performance, audit and enforcing the regulations through inspection and surveillance from production to the final consumers (33).

As in other countries worldwide, GMP is mandatory requirement to all food industries in Tanzania. TFDA is obliged by the law to enforce implementation of GMP in food industries in the country (7). In order to facilitate GMP implementation and compliance in food manufacturing industries, TFDA developed the guidelines for Good Manufacturing Practices in 2013 (6). Food manufacturers, including small scale maize millers, are required to abide by the requirements stipulated in these guidelines. The guidelines complement various food products safety and quality assurance measures from beginning to the end of the production process. It is also used as the basis for registration of premises, registration of food products and licensing of food manufacturers in Tanzania. Maize millers are required to comply with these guidelines prior being issued with registration of premises certificate and business

licenses. This study determined the factors that affected GMP compliance in Ubungo and Kinondoni districts. These factors were low level education of the millers, lack of guidance from TFDA, use of rented building and poor GMP supervision by TFDA in Ubungo and Kinondoni Districts because of low financial and human resources. If these issues addressed would improve the implementation of GMP requirements in Tanzania.

### **2.1.1 Importance of GMP implementation in Maize Milling Industry**

Failure to comply with GMP in maize milling industries can threaten human health because of food borne illness (2,27). This is because maize flour is the main cereal product consumed by majority of Tanzanians, and is prone to physical, chemical and microbial contaminants if GMP is not adhered (28). It is estimated that maize consumption accounts for 16% of the National household food expenditure, and in comparison with other cereals consumption, maize is leading by 75% and on average 400g of maize is consumed/person/day. The average annual national maize consumption is over 3, 000,000 metric tons (23,24,25,19). Some of the foodborne diseases caused by contaminated maize and maize flour are diarrhea, aflatoxicosis cancer, immune system suppression, growth retardation and liver diseases (19,20,21). In Kenya aflatoxin B<sub>1</sub> outbreak resulted into killing of 191 people and morbidity of 477 people (22).

The global health threat to consumers of maize flour is on chemical toxicants because most of them cannot be removed/ reduced from food by normal cooking, and the most predominant toxicants are mycotoxins (29). In developing countries, major contaminant in maize during farming and storage are mycotoxins. In Gedeo Zone of Ethiopia prevalence of aflatoxin is 100% with levels above the recommended levels set by FDA and EFSA (30). In western Kenya, prevalence of aflatoxin is 41% with 4% over the regulatory limit while prevalence of fumonisin, is 50% over the regulatory limit (31). In Kaduna State, prevalence of aflatoxin is 82.7% above the tolerance level established by WHO (20).

In 2012, prevalence of aflatoxin in maize in Tanzania were 57% in Eastern Zone, 15% in North, 2% in South, 12% in Southern Highlands, 70% in the West (ABT associates, 2012) and



levels up to  $158 \mu\text{g kg}^{-1}$  were detected in 2015 (32). Study done in Kilosa found high levels of fumonisins in maize range from 70.46 to 213.15  $\mu\text{g/kg}$  (33). Maize flour can also be contaminated with other contaminants such as heavy metals whereby higher levels of nickel and lead than the recommended limits found in some districts (up to  $56.9 \text{ mg kg}^{-1}$  and  $>0.2 \text{ mg kg}^{-1}$ )(34). Pesticides residues in maize found to be below than the set levels however, their risk shall not be ignored since farmers in Tanzania have been reported to intensively use hazardous chemicals in farming which can endanger human health (35).

Apart from microbial and chemical contaminants, maize flour is prone to physical contaminants such as dust, stones, debris and other unwanted materials during processing and storage. Therefore, there must be a mechanism in place, during processing, aiming at reducing the population from exposure to these chemicals. It has been advised to follow GMP during processing so as to reduce mycotoxin levels to safe levels (32). Moreover, maize flour in Tanzania is commonly used for cooking of porridge or *ugali*. Therefore, maize food if is well cooked, the risk of getting food infection and or diseases is reduced. The global health threat to consumers of maize flour is on chemical toxicants because most of them cannot be removed/ reduced from food by normal cooking and the most pre dominant toxicants are mycotoxins.

Therefore, it has been advised to abide by GMP during processing so as to reduce mycotoxin levels to safe levels (33).The findings of this study provide information on adherence with GMP among small scale maize milling industries in Kinondoni and Ubungo districts.

### **2.1.2 Categorization of GMP in Maize Factories**

In Tanzania, GMP requirements in maize milling industries have been categorized into requirements for location and building, requirements for water, sanitation and staff hygiene, requirements for raw material and quality testing, requirements for food equipment and process and requirements for records (8).

For location and building, the milling industries is required to be situated within industrial area, free from sources of contamination, accessible by road with sound surface water drainage

system in place. The building must be constructed with permanent material and of good state of repair, adequate air ventilation provided to prevent dust explosion. The floor shall be hard, smooth, non-absorbent with no accumulation of dirties or dust. The rooms must provide adequate area to accommodate activities carried on. The floor shall be of good water drainage in such a way that it prevents water stagnation. The walls shall be internally plastered and the roof or ceiling has no leakage (6,8).

Furthermore, water supply must be potable and available at all time with adequate volume and pressure. Adequate water supply is necessary during production and in sanitation and staff hygiene. Also, there must be sufficient number of toilets available with hand washing facilities, proper sewage and drainage facilities. Cleaning schedules and methods must be followed and dressing rooms with lockers should be present and kept clean. Additionally, there must be a mechanism of controlling pest infestation. Millers must be competent and must be medically examined on first appointment and after every six months. During processing they should be provided with clean protective clothing (6,8).

In addition, maize grains shall be analyzed and stored in a ventilated area. All contact surfaces required to be clean and well designed. After processing, maize flour shall be properly packaged in a suitable food grade material and labeled accordingly. After milling product need to be tested for quality assurance before distribution. Insect and rodent shall be controlled along the processing line up to the storage of processed products and pesticides shall be stored separately and must be labeled. Records for quality control test of raw materials and finished products, medical examination of employee and cleaning disinfestations schedule shall be kept (6,8). In this study, all of these requirements were assessed using the observation checklist.

## **2.2 Maize miller's factors associated with GMP compliance**

### **2.2.1 Knowledge on GMP among maize millers**

Lack of knowledge among small scale maize millers hinder implementation of GMP because GMP compliance requires competent personnel to deal with legal requirements, interpret and implement necessary controls. Lack of knowledge and experience in GMP makes manufacturers to find it complex to implement (37,13,38). The study to assess food safety management practices of small and medium sized food industries in Tanzania revealed that the level of knowledge of the processors on GMP was 64.3%, which is almost similar with the study done in UK (50%) whereby 32% were unaware and 40% did not understand its importance. The study done in Turkey found 92.2% of small scale processors were not aware of GMP. In Sri Lanka, 68% of confectionaries small scale manufacturers had knowledge on GMP. However, in UK and Turkey, processors where implementing HACCP system (15,13,39,40).

It was reported that, even if training program is introduced to processors, knowledge problem will still persist due to high staff turnover. Needless to say, small scale processors have been found not to be familiar with relevant laws and regulations and their employers do not see the importance of training. It was found in Kenya that lack of skills was a factor for poor performance of food safety management practices among small scale food processors.

Manufacturers' perceptions towards compliance to GMP requirements are directly related with knowledge in food safety. Therefore, it is vital importance for the small scale maize millers to have adequate knowledge concerning good manufacturing practices (37,39,40). This study did not assessed knowledge on GMP among maize processors but instead it assessed awareness on GMP and if they were trained on GMP. It was found that, all millers were aware on GMP and majority were trained on GMP requirements. However, training on GMP requirements found not to influence compliance in the study area.

### **2.2.2 Ability of millers to meet compliance cost**

Low financial capacity among small scale food manufacturers limits them to effectively implement GMP. Manufacturers are willing to comply when the benefit of compliance outweighs the cost incurred because their primary aim is to enter into food business is to generate profit. Apart from low financial capacity, lack of awareness on food safety issues to consumers in developing countries including Tanzania fuels low GMP compliance (1,9,15,38,41). It has been observed in Sri Lanka and India whereby small scale manufacturers fails to improve their premises due to lack of capital (40,18). In developed countries, compliance cost to GMP is not a problem. However, small scale manufacturers fails to meet other food safety management systems for instance in UK, 16% manufacturers reported to be constrained with high cost for compliance with food safety regulations (37).

In the National Policy for Small and Medium Enterprises of 2003, financial capacity mentioned to be a constrain for development of SME's. Therefore, this study assessed if millers were facing similar constrain in the effort to comply with GMP requirements.

### **2.2.3 Lack of training**

Food manufacturers should be regularly trained for the purpose of continuous improvement of GMP requirements despite his/her pre-qualification before employment. Training helps to increase compliance levels for instance training of food processors in Poland raised compliance level from 56% to 77% (12). A study on aflatoxin control and prevention strategies in maize for Sub-Saharan Africa suggests that, training to maize millers is inevitable for control of mycotoxins so as to adhere with GMP in milling (42). Another study indicates that lack of onjob training to food processors is the main barrier to improvement of food safety management systems in countries such as India, Sri Lanka, USA and most of developing countries (18, 43, 40). This study also assessed if training is the problem to maize flour processors in Ubungu and Kinondoni districts.

#### **2.2.4 Lack of support**

In order for manufacturer to comply with legal requirements they need get all necessary support from regulatory Authorities and that shall go hand in hand by being supervised by food inspectors. UK Small scale manufactures reported to fail to meet safety regulatory requirement because of lack of support and perceived that their government is biased because it support more large manufacturers than them (15). The same has been reported in developing countries. In Tanzania, TFDA was among of the government institution which was claimed to fail to effectively support small scale food manufacturers to produce food which its safety is guaranteed (41). Therefore, lack of support from TFDA was also assessed in this study.

#### **1.1.1 Law enforcement**

In many countries, food safety laws and related regulations are used as tool for ensuring safety of food. However, enforcement of these legislations is problematic in many countries of the world. Effective enforcement is the driver of regulatory compliance (23). Poor law enforcement by food safety control agencies was reported to be a problem of compliance by small scale food processors in China. The same was revealed in low and middle income countries such as Sri Lanka where by small scale confectioneries manufacturer not achieved minimum requirement for quality management due to negligence and not being conscious on GMP during processing because of weak enforcement (27,40).

Government enforcement tools include seizure, ban, penalties and imprisonment. In order for the GMP compliance be realized, small scale food manufacturers who fails to abide with GMP regulations are supposed to be highly punished using these tools. It was reported that, the fines paid by small scale manufacturers who fails to abide with the regulations were very low in comparison with the profit that they make (37). Since in Tanzania there are legal actions that have to be taken to millers if they fail to adhere with the regulations, this study assessed the influence of legal actions and GMP compliance.

### **2.3 Small scale maize millers' opinion on GMP requirements**

Information regarding small scale maize miller's opinion on GMP implementation is important in planning of intervention activities. In most of developing countries small scale manufacturers' opinions found to be negative in implementation despite of being considered useful for quality improvement. They claimed that some of GMP requirements are difficult to be implemented. For instance, in Sri Lanka small scale confectioneries manufacturers failed to comply with the requirement of location and design of premises, hygiene and sanitation. GMP guidelines require the room to provide adequate area to accommodate activities carried and should be separate building but their premises do not provide separate building, processing is done within available space in their houses in which hygiene and sanitation requirements were not fulfilled. The main reason for such failure is perception that they are difficult to be implemented (40).

Based on these findings, this study also found out small scale millers opinion on GMP requirements in Kinondoni and Ubungo District to see if had similar or different views with regards to GMP requirements.

### **2.4 Factors that affect GMP supervision by regulatory Authorities**

Regulatory authorities are required to have the capacity to effectively support and conduct audit inspections to small scale maize millers to facilitate compliance with GMP requirements. They need to ensure maize millers products are registered. They also have to make sure surveillance system is strengthened, raise public awareness on food safety issues, provide advice and taking legal actions in case of disputes. All these are proven to trigger GMP compliance. Also, training of food inspectors must be emphasized so that to capacitate them with food processing technologies and their powers under the laws (1).

However, in low and middle income countries including Africa, small scale food processors fail to comply with legal requirements because of weak regulatory capabilities of regulatory authorities (27,44,45). Regulators are faced with challenges of inadequate number staffing, technical capacity, political pressure and insufficient financial resources (1,23). It has further been revealed in other study that focused on regulatory monitoring of fortified foods that 50%

of the respondents from regulatory authorities reported weak regulatory capability to monitor compliance in industries. The main reported reasons were unclear regulations-71%, poor regulatory agency structure-57%, low financial capacity-43%, low penalties-7%, poor technical expertise-65and limited human resource-72% (11). Since Tanzania is in Africa, poor supervision by the regulatory Authority (TFDA) also can be a problem to GMP compliance among small scale millers in Ubungo and Kinondoni Districts. Therefore, this study assessed this factor to see if this assumption was true.

Generally, this study found proportion of registered small scale maize milling industries of Ubungo and Kinondoni Districts that complied with GMP was 21.9%. The main factors that influenced low GMP compliance were low level education among millers, lack of guidance from TFDA and use of rented buildings.

## CHAPTER THREE

### 3.0 METHODOLOGY

#### 3.1 Study area

This study was conducted in Ubungo and Kinondoni Districts, located in western part of Dar es Salaam city. Ubungo district comprises of 14 wards while in Kinondoni there are 20 wards. The two districts had a total number of 157 registered small scale maize milling industries which commercially pack maize flour. These districts were chosen for this study because they had many registered small scale maize millers than any other district in Dar es Salaam.

#### 3.2 Study design

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

#### 3.3 Study population

The study population was owners of small scale maize milling industries who are registered by TFDA and commercially pack maize flour Ubungo and Kinondoni districts. Also, the study included food inspectors from TFDA Eastern Zone Office.

#### 3.4 Sample size

##### 3.4.1 Sample size for small sale maize millers

The sample size for small scale maize millers was determined by using a formula:

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

Where;

P = Proportional of small scale maize millers who do not comply with GMP. Since proportion was not known in Tanzania or in any of the developing countries, 50% has been used.

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

E = Margin of error 7% (0.07).

$$n = \frac{1.96^2 * 0.5(1 - 0.5)}{0.07^2}$$

n = 196



Then 10% was added for non-response rate.

Therefore, the minimum estimated sample size for millers was 216. However, only 157 were found found to be registered in both districts and 155 agreed to participate in the study.

### **3.4.2 Sample size for TFDA inspectors**

A total of 3 inspection supervisors at TFDA Eastern Zone Office participated in the study.

### **3.5 nclusion and exclusion criteria**

#### **Inclusion criteria**

- a. All registered small scale maize milling industries which commercially packed maize flour.
- b. All owners or most informed person of the registered small scale maize milling industries which commercially packed maize flour.
- c. All food inspectors at TFDA-Eastern Zone Office (EZO).

#### **Exclusion criteria**

- a. The owner or most informed person of the registered milling industries who was not exposed to GMP by TFDA.
- b. Food inspectors at TFDA-EZO who have never conducted inspection in small scale maize milling industries.

### **3.6 Sampling procedure**

#### **Sampling procedures for quantitative data**

The list of registered small scale maize milling industries that are registered and commercially pack maize flour from all wards in Ubungo and Kinondoni districts was obtained from TFDA register book at Eastern Zone Office and at Ubungo and Kinondoni Municipal Councils. Reconciliation was done so that to get the actual list after been found that there were duplication of the facilities between the councils and TFDA. After reconciliation of the two lists, a total of 157 milling industries were listed and all were selected to participate in the study. Their names and physical addresses were recorded so that the owners could be easily be contacted during data collection.

### **Sampling procedures for qualitative data**

To find out the factors that affect GMP supervision by TFDA in Ubungo and Kinondoni districts, all (3) inspection supervisors at TFDA Eastern Zone Office were selected purposively for in depth interviews and all of them were interviewed.

### **3.7 Data collection tools**

- a. GMP observation checklist was used to collect data on the proportion of GMP compliance.
- b. Questionnaire with closed and open ended questions was used to collect data from registered small scale millers' on GMP implementation and millers' opinion on GMP requirements.
- c. Interview guide was used to collect data on factors that affect GMP supervision by TFDA.

### **3.8 Selection and training of research assistants**

Six food scientists with experience in research were recruited as research assistants. They were trained and familiarized with the study objectives and how to collect data using the tools provided.

### **3.9 Pre testing of the data collection tool**

The GMP observation checklist and Kiswahili version of questionnaire were pretested in 2 small scale maize milling industries in Ilala district and interview guide was pretested in 2 food inspectors from TFDA headquarter respectively, to check if the questions were relevant, understood, consistent, properly sequenced and logical to generate valid and reliable information. Necessary corrections to the questions were made before data collection.

### 3.10 Variables and definition

Variable	Description
<b>Dependent variable</b>	
GMP compliance (Yes/No)	Yes = 1, No = 0
<b>Independent variables</b>	
Level of education	$\leq$ Primary education = 1, $\geq$ Primary education = 0
Trained on GMP (Yes/No)	Yes = 1, No = 0
Able to meet compliance cost (Yes/No)	Yes = 1, No = 0
Had guidance from TFDA in the past 12 months (Yes/No)	Yes = 1, No = 0
Faced legal actions (Yes/No)	Yes = 1, No = 0
Ownership of business building	Rented=1, owned by the miller = 0
Maize source	Sourced from wholesalers=1, else=0
Necessity of GMP in milling (Yes/No)	Yes = 1, No = 0
GMP difficult to implement (Yes/No)	Yes = 1, No = 0
Has human resource capacity (Yes/No)	Yes = 1, No = 0
Has financial capacity (Yes/No)	Yes = 1, No = 0
Technical capacity (Yes/No)	Yes = 1, No = 0

### **3.11 Validity and reliability of data collection tools**

Internal validity was observed by using standard data collection tools; TFDA GMP observation checklist, questionnaire and interview guide. All the tools were pretested in small scale maize milling industries in Ilala district where necessary adjustments were made in the questionnaire and interview guide. Thereafter, questionnaire and interview guides were translated into Kiswahili language and finally Kiswahili versions were used to conduct interviews. The language used for interviews was Kiswahili.

Reliability of the tools was assured by using competent research assistants and pretesting of the tools. All research assistants were trained and familiarized with the research objectives and data collection tools.

### **3.12 Data collection procedures**

#### **Data collection at milling industries**

Prior the visit to the study area, each member of the research team was provided with the particulars of the industries that he/she supposed to conduct the survey on a particular day. At the milling premise, the researcher interviewed the owner of the business or the most informed person using a questionnaire with closed and open ended questions to find out the miller's characteristics and reasons that affect GMP compliance and their opinion on GMP requirements. Thereafter, a researcher visited the factory to observe the premises using the GMP observation checklist (Appendix V).

#### **Data collection at TFDA Eastern Zone Office**

The researcher visited at TFDA Eastern Zone Office. Food inspectors were interviewed using the interview guide (Appendix III). The interviewer was asked key questions and probes were made regarding TFDA capability to regulate registered small scale maize millers in Ubungo and Kinondoni Districts. During the interview, the information provided by the inspector was recorded and noted. At the end, the interviewee was asked if he/she has any additional information and finally was thanked for participating in the study. The same procedure was followed to subsequent interviewees.

### **3.13 Data management**

Data collected was sorted and checked on daily basis to check see the accuracy and precision of data among researchers and also to check for ambiguities. In case of any missing information or inconsistency, the interviewer went back to the particular study unit to make necessary adjustment. Missing information occurred in 8 questionnaires and 2 observation checklists. Thereafter, data collected were coded and then entered into Statistical Package (Social Sciences (SPSS) version 20) and cleaned to minimize errors and detection of any abnormalities.

### **3.14 Data analysis**

After data cleaning, the data was analysed using the same statistical package. Descriptive statistics such as frequencies and means were used to summarize and describe the data. The percentage of total scores obtained from the GMP checklist (Appendix V) determined the proportion of GMP compliance. Each GMP requirement in the checklist had a score therefore the total score was obtained by taking the summation of scores of each element within the requirement. The sum of the scores provided information on the proportion of compliance of that particular milling factories: those who scored 65-100% were considered as GMP compliant and those who scored below 65% were regarded as GMP non-compliant. However, the factory that scored 0 in any of the critical defects (adequate ventilation, maize grains condition, and presence sufficient number of toilets with hand washing facilities) automatically considered as GMP non compliant (6,8).

Cross tabulation was done to determine relationship between all independent variables and level of GMP compliance as dependent variable. Bivariate and univariate analysis of all independent variables that showed strong relationships with dependent variable ( $P= 0.05$ ) were included in the multivariate analysis using a logistic regression model.

The data collected from inspectors at TFDA Eastern Zone Office were analysed using thematic analysis method. Collected data in form of written notes and audio tapes were reviewed and transferred in MS word computer program in organized tabulated form. Then,

the information obtained were critically analyzed thematically to identify significant patterns. Sentences that answers research question from each pattern highlighted and coded. Coding involved organizing and compressing the assembled information to make sense of the collected data. Finally, themes were generated from the codes.

### **3.15 Ethical considerations**

Ethical clearance was requested from Muhimbili University of Health and Allied Sciences research and publication Committee for conducting the research. Letters to seek permission to conduct the research were sent to the Municipal Directors of Ubungo and Kinondoni Municipalities. Participants were given written informed consent form to make informed consent to participate in the study. The consent provided information on the purpose of the study and the method that was used for data collection from the participants and it provided assurance of confidentiality to study participants. They were informed about their rights to autonomy and they were told about the benefits and risks of their participation in the study (Appendix VIII).

## CHAPTER FOUR

### 4.0 RESULTS

#### 4.1 Characteristics of the premises and respondents

Data were collected from all registered small scale maize milling industries located in Ubungo and Kinondoni Districts, and their respective owners. Initially, a total of 157 premises were involved in the study. Among them, 2 refused to participate in the study, so 155 were finally interviewed. Additionally, 3 senior food inspectors from TFDA-Eastern Zone Office were interviewed.

##### 4.1.1 Characteristics of the premises

Table 1 shows characteristics of the premises involved in the study. Out of 155 small scale milling industries, 95(61%) were located in Ubungo district and 60 (39%) in Kinondoni district. Majority 124 (80%) of these industries were rented and only 31 (20%) owned by millers. Almost all milling industries were not managed by qualified personnel 152 (98%). Only 6 (4%) out of 155 milling industries produced at least one maize flour product that had been approved by TFDA, while the rest (96%) produced maize flour which were not approved by TFDA. The mean number of employees working as processors in these industries was 5(SD±2.53), median was 5 with a range of 1-16 employees.

**Table 1. Characteristics of the premises**

<b>Variable</b>	<b>Frequency (n)</b>	<b>Percentage (%)</b>
<b>Location/District</b>		
Ubungo	95	61
Kinondoni	60	39
<b>Ownership of the building</b>		
Rented	124	80
Not rented	31	20
<b>Management</b>		
Qualified personnel	3	2
Non-qualified personnel	152	98
<b>Product approval status</b>		
At least one product approved	6	96
No product approved	149	4
<b>Number of employees</b>		
1-4	72	47
5-8	73	47
9-12	8	5
13-16	2	1

#### **4.1.2 Socio-demographic characteristics of the millers**

Table 2 shows socio-demographic characteristics of the registered small scale maize millers. Out of 155 registered small scale maize millers were interviewed, 126 (81.3%) were owners of the milling factories and 29(18.7%) were representatives of the owners. Their mean age was 39.66 (SD±8.06), median age was 40 ranging from 21-65 years. The number of female respondents was higher 99(63.9%) than 61(36.1%) male respondents. Out of these women, 82(82.8) were owners and 17(17.2) were representatives. Most of the millers had working experience of less or equal to 5 years (33.5%) and between 6-10 years (40.6%). Majority (60%) had completed primary education. For those who had completed tertiary education (3.2%), none of them had a profession in food technology and or related fields.



**Table 2. Socio-demographic characteristics of the respondents**

<b>Variable</b>	<b>Frequency (n)</b>	<b>Percentage (%)</b>
<b>Age</b>		
20-30	29	18.7
31-40	61	39.4
41-50	51	32.9
51-60	12	7.7
≥61	2	1.3
<b>Position</b>		
Male owner	44	28.4
Male representative	12	7.7
Female owner	82	52.9
Female representative	17	11.0
<b>Level of education</b>		
No formal education	13	8.4
Primary education	93	60.0
Secondary education	44	28.4
Tertiary education	5	3.2
<b>Working experience</b>		
≤5	52	33.5
6-10	63	40.6
11-15	23	14.8
16-20	15	9.7
≥21	1	0.6

### 4.1.3 Socio-demographic information of food inspectors

Food inspectors of TFDA-Eastern Zone Office who were interviewed were aged 36, 38 and 39 years respectively and among them 2 were male and 1 female. Their education levels were; 2 had a bachelor degree in Food Science and Technology while 1 own masters degree in Food Safety and Public Health. All have a working experience of 5 to 10 years.

## 4.2 GMP compliance

### 4.2.1 Distribution of compliance scores

Table 3 shows the distribution of compliance scores among registered small scale milling factories. The scores were obtained by summing up all the scores in each GMP items as prescribed in the observation checklist (Appendix V). The mean score in the two districts was 54.5(SD±12.2). Majority of the industries scores ranged between 41% and 70%. Minimum score was 25% and the maximum was 82%.

**Table 3. Distribution of GMP compliance scores**

Scores (%)	District		Total n (%)
	Ubungo n (%)	Kinondoni n (%)	
20-30	2 (2.1)	2(3.3)	4(2.6)
31-40	2 (2.1)	10(16.7)	12(7.7)
41-50	27 (28.4)	21(35.0)	48(31.0)
51-60	26 (27.4)	9(15.0)	35(22.6)
61-70	27 (28.4)	13(21.7)	40(25.8)
71-80	10 (10.5)	5(8.3)	15(9.7)
≥80	1(1.1)	0(0.0)	1(0.6)

Mean score was 54.5(SD±12.2), median 54 with a minimum of 25 and a maximum of 82

#### 4.2.2 Good Manufacturing Practices compliance level

Table 4 shows GMP compliance in registered small scale maize milling industries. More than three quarters (78.1%) of the milling industries were found to be GMP non-compliant. The cutoff score as set by the Regulatory Authority (TFDA) was 65%. There was no significant difference between small scale maize millers of Ubungo and Kinondoni on compliance with GMP (**P=0738**).

**Table 4. Good Manufacturing Practices compliance level in registered small scale maize milling industries of Ubungo and Kinondoni Districts**

District	GMP compliance			P-value
	Yes n (%)	No n (%)	Total n (%)	
Ubungo	20(21.1)	75(78.9)	95(100.0)	0.738
Kinondoni	14(23.3)	46(76.7)	60(100.0)	
<b>Total</b>	<b>34(21.9)</b>	<b>121(78.1)</b>	<b>155(100)</b>	

#### 4.2.3 Compliance of location, building, water and sanitation requirements

Table 5 shows observations of factory requirements for compliance to Good Manufacturing practices among registered small scale maize milling industries of Ubungo and Kinondoni Districts. All premises were not located within industrial areas, but all were accessible by road and built of permanent materials with hard non-absorbent floor finish. Only one premises was found to be located away from sources of contamination. Majority had no sound surface water drainage in place 126(81.3%), 130(83.9%) had no adequate ventilation, 118(76.1) had inadequate space and 134(86.5%) had no sound sewage and waste water disposal. Also, a total of 15(9.7%) factories were found not to have toilets at all.

**Table 5. Compliance with location, building, water and sanitation requirements**

Observations	Compliance	
	Yes	No
<b>Location*</b>		
Located within industrial area	0(0)	155(100)
Away from sources of contamination	1(0.6)	154(99.4)
Accessible by road	155(100)	0(0)
Sound surface water drainage in place	29(18.7)	126(81.3)
<b>Building structure*</b>		
Of Permanent material	155(100)	0(0)
Of good state of repair	83(53.5)	72(46.5)
Adequate air ventilation	25(16.1)	130(83.9)
Floor finish is hard	155(100)	0(0)
Floor finish smooth	102(65.8)	53(34.2)
Floor finish is non-absorbent	155(100)	0(0)
Room provides adequate area	37(23.9)	118(76.1)
Roofing or ceiling has no leakage	96 (61.9)	59(38.1)
Walls internally plastered/painted	116(74.8)	39(25.2)
<b>Water availability*</b>		
Use of draining water, private and available all the time	37(23.9)	118(76.1)
<b>Sanitation facilities*</b>		
Presence of toilets	140(90.3)	15(9.7)
Sufficient number of toilets	47(33.6)	93(66.4)
Hand washing facilities	50(32.3)	105(67.7)
Sound sewage and waste water disposal	21(12.9)	134(86.5)

\*Multiple observations

#### **4.2.4 Compliance of equipments, process, sanitation and staff hygiene requirements**

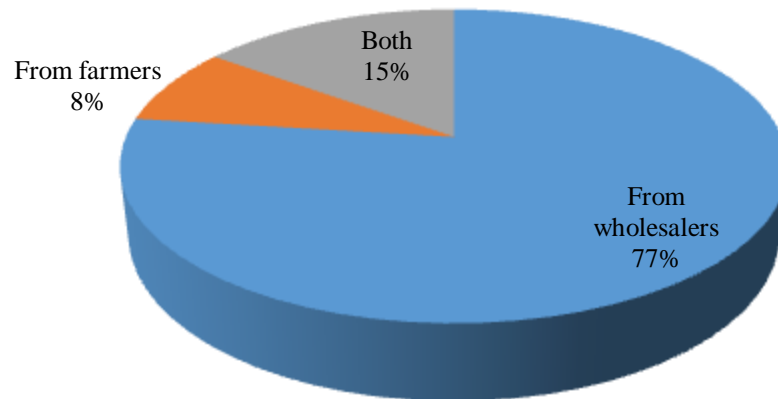
Table 6 shows observations of more requirements on compliance to Good Manufacturing practices in the study premises. Majority of the factories had not complied to most of the requirements, however they had complied to packaging material (100.0%), medical examination of employees after every six months (84.7%) and medical records keeping of employees (81.9%). During assessment, maize quality was examined physically and about 120(77.4%) milling industries found to have maize quality of good quality. Performance of other factory requirements is as shown on the table 5.

**Table 6. Compliance with equipments, process, sanitation and staff hygiene requirements**

Observations	Compliance	
	Yes	No
<b>Equipment and process*</b>		
Food contact surfaces clean	53(34.2)	102(65.8)
Non food contact surfaces be well cleaned	25(16.1)	130(83.9)
Proper insect and rodent control	31(20)	124(80.0)
Maize in sound condition	120(77.4)	30(22.6)
Milling process is adequate to prevent contamination	0(0.0)	155(100.0)
Food products properly packaged	155(100.0)	0(0.0)
Food products properly labeled	23(14.8)	132(85.2)
<b>Sanitation and staff hygiene*</b>		
Clean toilets	18 (12.9)	122(87.1)
Employees medically examined on first appointment	5(3.2)	150(96.8)
Employees medically examined after every six months	127(84.7)	28(15.3)
Employees provided with clean protective clothing	31(20)	124(80)
Cleaning schedules present	7(4.6)	148(95.4)
Dressing rooms provided	36(23.2)	119(76.8)
Dressing rooms kept clean	3(1.9)	152(98.1)
Evidence of quality control test records	2(1.3)	153(98.7)
Medical examination records	127(81.9)	23(18.1)
Cleaning disinfection/ disinfestations	64(41.3)	91(55.7)

\*Multiple observations

Figure 2 shows the sources of maize stock by registered small scale maize millers. Out of 155 millers, 119(77%) get their maize from wholesalers, 13(8%) from farmers and 23(15%) from both retailers and farmers.



**Figure 2 Figure 2: Sources of maize stock by registered small scale maize millers**

#### **4.3 Small scale maize millers' characteristics by GMP compliance**

Table 7 shows small scale maize millers' characteristics by GMP compliance. Results show that there were significant difference between GMP compliance and level of education (**P=0.001**), support from TFDA (**P=0.001**), facing legal actions (**P=0.007**), ownership of the premises (**P=0.005**) and opinion on difficultness of GMP requirements at **P<0.001**.

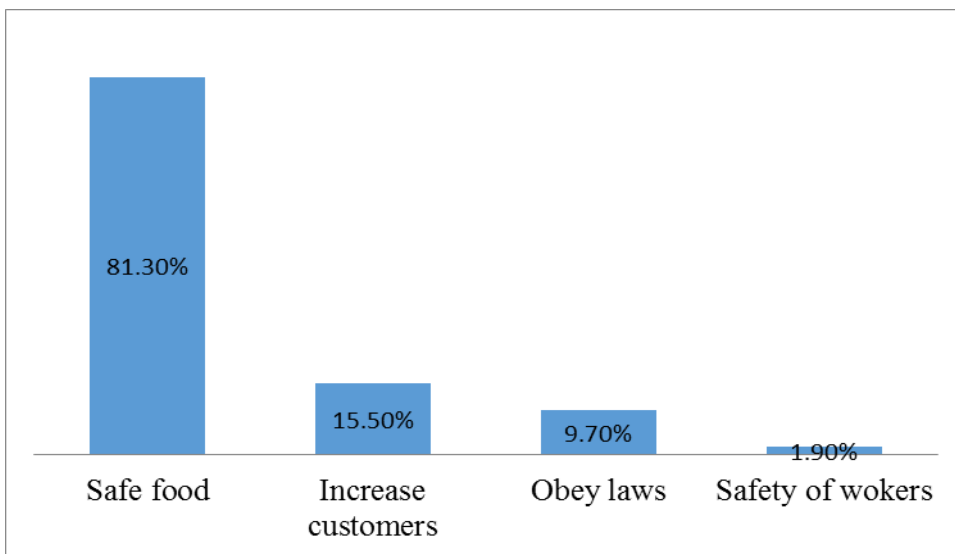
**Table 7. Small scale maize millers' characteristics by GMP compliance**

Variable	GMP compliance			P-Value
	Yes	No	Total (n)	
<b>Level of education</b>				
≤Primary education	4(13.9)	87(86.1)	101	0.001*
≥Secondary school	20(37.0)	34(63.0)	54	
<b>Training on GMP</b>				
Yes	18(25.4)	53(74.6)	71	0.345
No	16(19.0)	68(81.0)	84	
<b>Ability to meet compliance cost</b>				
Yes	20(28.2)	51(71.8)	71	0.085
No	14(16.7)	70(83.3)	84	
<b>Guidance from TFDA in past 12 months</b>				
Yes	23(34.8)	43(65.2)	66	0.001*
No	11(12.4)	78(87.6)	89	
<b>Faced legal actions in past 12 months</b>				
Yes	10(29.4)	13(10.7)	23	0.007*
No	24 (70.6)	108(89.3)	132	
<b>Building ownership</b>				
Rented	18(14.4)	107(85.6)	125	0.000*
Owned by miler	16(53.3)	14(46.7)	30	
<b>Employed ≥ 1 GMP trained staff</b>				
Yes	9(26.5)	25(73.5)	34	0.612
No	27(22.3)	94(77.7)	121	
<b>Necessity of GMP in milling industries</b>				
Yes	31(22.1)	109(77.9)	140	0.477
No	3(21.4)	11(78.6)	14	
<b>Difficult to fulfill GMP requirements</b>				
Yes	16(14.7)	93(85.3)	109	0.001*
No	18(39.1)	28(60.9)	46	



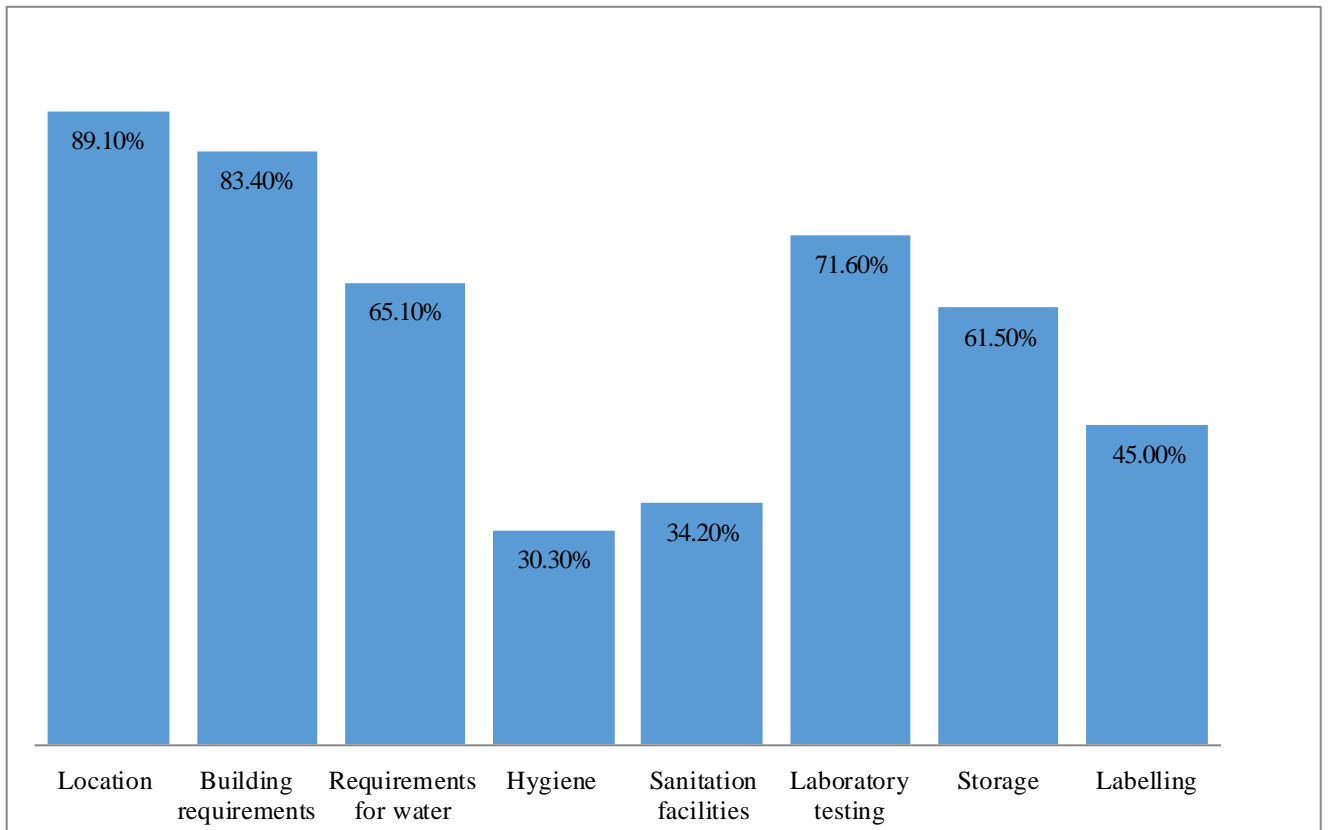
#### 4.4 Millers' opinion on GMP requirements

Figure 3 show small scale maize millers opinion on the importance of GMP in milling industries. Proportion of (81.9%) millers who reported that GMP requirements were for safety of the maize flour that was produced, while 15.5% said it helped to increase customers, 9.7% said it is the requirement of the law and 1.9% said that it helped to assure safety of workers during milling.



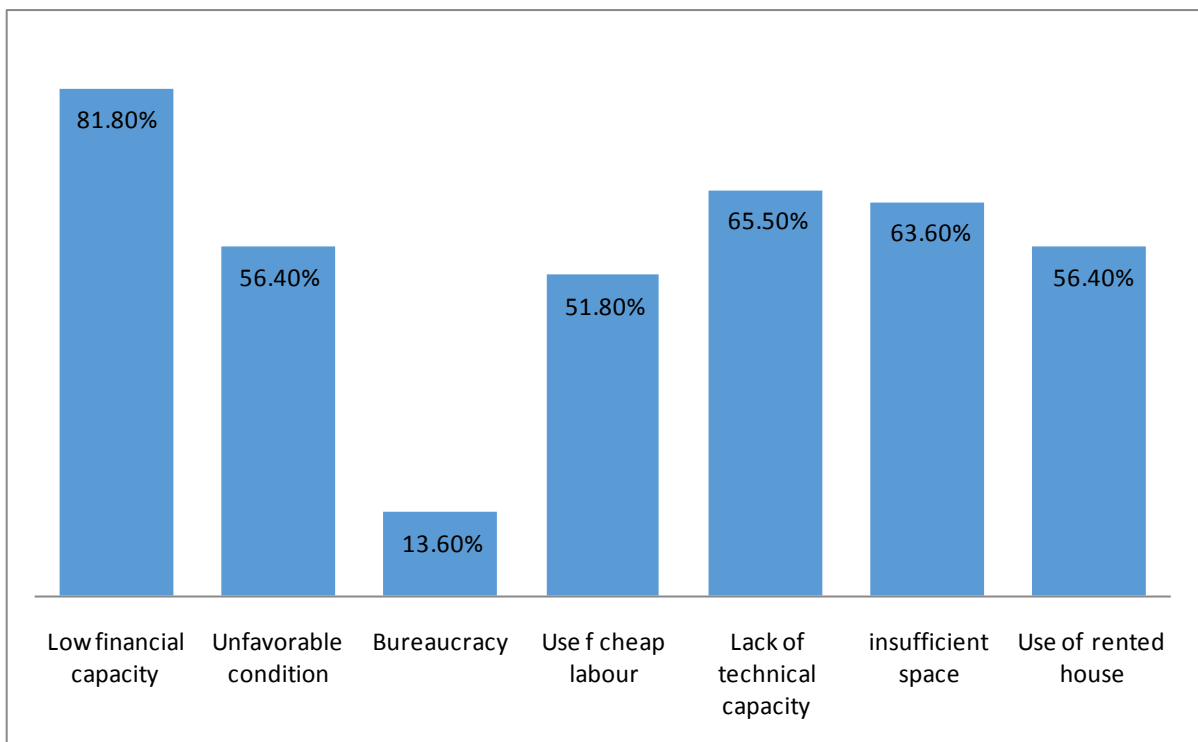
**Figure 3. Opinion of small scale maize millers on the necessity of GMP**

Figure 4 shows millers' opinion on which GMP requirements they perceived as difficult to implement. Majority perceived location requirements (89.1%), building requirements (83.4%), water requirements (65.1%) and laboratory analysis (71.6%) was difficult to implement and 61.5% perceived requirements for storage were difficult to implement.



**Figure 4. Millers' opinion to which GMP requirements they perceived as difficult to implement**

Figure 5 shows reasons provided by millers as to why they perceived GMP requirements were difficult to be implemented. Majority of the millers (81.8%) said because of low financial capacity; 56.4% said because of unfavourable conditions; 51.8% said due to use of cheap labour; 65.5% said because of lack of technical capacity; 63.6% said it is due to insufficient space and 56.9% said because they operate in rented buildings.



**Figure 5. Reasons provided by millers as to why they perceived GMP requirements were difficult to implement**

#### 4.5 Determinants of GMP compliance

Table 8 shows regression analysis of GMP compliance (dependent variable) and independent variables. The results show that millers who were guided by TFDA in the past 12 months were 5.54 times more likely to comply with GMP requirements while millers with primary education and below were 69% less likely to comply with GMP requirements. Also, millers who used rented buildings were 93% less likely to comply with GMP requirements.

**Table 8. Determinants of GMP compliance**

Variable	Category	n	Crude OR		Adjusted OR	
			OR (95% CI)	OR (95% CI)	P-value	
<b>Level of education (<math>\leq</math>Primary)</b>		101	0.27(0.12-0.60)	0.32(0.12-0.84)	0.021*	
<b>Guided by TFDA</b>		66	3.46(1.69-8.52)	5.54(1.51-13.14)	0.007*	
<b>Faced legal actions in the past 12 months</b>		23	3.46(1.36-8.82)	2.06(0.62-6.82)	0.235	
<b>Rented building</b>		125	0.15(0.06-0.35)	0.09(0.03-0.26)	0.000*	
<b>Difficult to fulfill GMP requirements</b>		109	0.48(0.12-0.59)	0.50(0.18-1.31)	0.150	

## **4.6 Factors that effect GMP supervision by the Regulatory Authority (TFDA)**

### **4.6.1 Human resource capacity**

All respondents reported that the number of food inspectors for supervision activities is not sufficient. The reasons provided for failure to effectively supervise the premises by all were almost similar: that they have many responsibilities that make them not to supervise small scale maize milling factories adequately. One of them confirmed by saying:

*“.....actually we few enough because we are also responsible to control importation and exportation in all ports of entry in Dar es Salaam and coastal region. We are also responsible to conduct inspection activities in food industries and in the markets. Apart from that we have to process customer’s applications, how can we manage all these while we are only 11?”*(Inspector no. 2).

### **4.6.2 Financial Capacity**

The respondent showed concerned on the budget allocated for supervision activities. They all confirmed that the budget allocated for supervision activities was inadequate. One of them had this to say:

*“Funds allocated to supervision are not enough to carry out audit inspection of all small scale food facilities in Eastern Zone. The budget should be increased...”* (Inspector no. 1).

Also, they further reported that, even if the budget is increased, new food inspectors should be first employed. One of them said:

*“...the budget should be increased together with increasing the number of food inspectors”* (Inspector no. 3).

### **4.6.3 Technical capacity**

All respondents were concerned about inadequacy of competent supervisors to supervise small scale maize millers effectively. Also, none of them had education level below a bachelors’ degree in food safety related fields and here, one had this to say:

*“All of us have good education background and professional knowledge that are related to control of food safety and quality.....ten of us have bachelor degrees in food science and*

*technology and 2 have master degrees in Food Safety and Public Health. The last one has master degree in Public Health and Food Safety”.* (Inspector no. 3).

Interviewed supervision they all had a working experience of more than five years in inspection activities, one confirmed by saying:

*“We are all not new here...no one has less than a year in this zone....”* (Inspector no. 3).

They also said that the organization provides on job training and also support them to go for further studies in the country and abroad, and here one had this to say:

*“a new inpector must be trained after being employed and we have a culture of having inhouse training for the purpose of continuous improvement of our services, we even go for short and long courses in and outside the country.Infact our employer is so supportive for that”* (Inspector no. 1).

## **CHAPTER FIVE**

### **5.0 DISCUSSION**

#### **5.1 Introduction**

This chapter discusses the results of the study. It provides the information on the issues related to GMP compliance in registered small scale maize milling industries of Ubungo and Kinondoni districts. The main finding of this study indicated that GMP compliance level among the study population was low. The main factors that influenced low GMP compliance were low education level, lack of sufficient guidance from regulatory Authority (TFDA) and use of rented premises among registered small scale maize millers.

#### **5.2 Proportions of compliance to Good Manufacturing Practices**

This study found that 78.1 % of small scale maize milling industries of Ubungo and Kinondoni Districts were not GMP compliant. Low compliance level might have been caused by failure of small scale maize millers to identify and interpret GMP guidelines and lack of motivation to comply. This implication was also in the study done in 2004 which show that, usually small scale food manufacturers depend on food inspectors for identification and interpretation of regulations (46). Also the complying may be observed only during the time of inspection. It may be that millers rarely understand the regulatory requirements and hence they cannot easily implement them.

The practice of shifting the responsibility of identification of their problems to regulatory authorities causes little motivation to improve further until they are told to do so in the next visit(46). Level of compliance could be high among registered small scale maize millers if they had qualified personnel responsible for identification and interpretation of GMP requirements.

Low GMP compliance level has also been found in the studies done in Kenya, Nigeria and some countries of South East Asia (9,10,11). Also low GMP compliance revealed in study done in noodles and fish industries in Indonesia were mainly influenced by poor hygiene and sanitation for workers, equipments and facilities of food (47). On the contrary, high

compliance to GMP had been found in Serbia (48), China, Poland, the Philippines and Egypt and Poland (12,49).

The approach used to determine compliance level in this study was different from the approach used by Fairman in 2004 in the study that assessed compliance level to the regulatory requirements. Fairman used case study design using quantitative and qualitative approaches based on compliance Process Model, which was developed in 1998 by Henson and Heasman(46). In that study, the manufacturer's compliance history to the regulatory authority was examined, then semi-structured interview was done in food factories with the owner or his/her representative to prove the compliance data obtained from the regulatory authority. Finally, compliance assessment of the factories was completed by establish current compliance levels. In comparison, the approach used to assess compliance level in this study was weaker than that of Fairman because it assessed compliance level at single point in time (cross sectional). The compliance level was lower (16%) than what found in this study (21.9%) possibly because of the study design they used(46).

Implication of low GMP compliance is the risk to consumers upon consumption of maize flour produced by these factories particularly to diseases associated with mycotoxin contamination. A number of studies have found that low compliance to GMP contributed to high prevalence of mycotoxin contamination which is the predominant chemical toxicants in maize flour (49,29).

Low level of compliance to GMP among small scale maize millers in Ubungo and Kinondoni districts can be improved if they shift to areas away from sources of contamination, improve infrastructure systems, have proper building designs, adequate sanitation and hygiene facilities, adequate milling process, proper labeling and reliable sources of water. Also; small scale maize millers need to be capacitated so as to be able to interpret GMP guidelines and its implementation.



### **5.3 Millers' factors that affect GMP implementation**

#### **5.3.1 Level of education**

In this study, majority of the millers had primary education and below. This study found that millers with secondary education and above were more likely to comply with GMP requirements than those with lower level of education. The main reason for this might be because of the GMP guidelines and relevant laws and regulations are written in English language which is easier understood by those have secondary education and above. Studies show that language barrier has been found to be a hindrance to compliance with GMP in low and middle income countries (47). These results collaborate the findings of the study done in Ghana in which processors with higher education level were twice likely to comply with mandatory food safety requirements (51), which has also been the case in China, Serbia, Italy, UK and the Phillipines where higher education level to manufacturers found to influence compliance to food safety management systems (49,48,52,53).

Since majority of the millers in this study have low level of education, TFDA is advised to translate GMP guidelines and relevant laws and regulations into Kiswahili language for easy understanding, interpretation and implementation.

#### **5.3.2 Training on GMP**

In this study all small scale maize millers were found to be aware of GMP. About half of them and less than a quarter of their employees were trained on GMP. However, training on GMP did not influence GMP compliance. This might be due to lack of willingness to affect changes, high staff turnover, lack of motivation, lack of commitment, and use of day workers. It is usual practice for small scale maize millers to engage in other activities than devoting their time for quality improvement and encouraging their staffs to practice on what they were trained on. In conditions such as these the importance of training on compliance cannot be realized (39). Apart from that, majority of the millers who were trained had low education level, therefore it might also be a reason for low compliance level to GMP by trained millers.

These findings were different from those found in the study done in Tanzania in selected food industries, where majority(73.9) of the manufacturers were trained on GMP (39) and in Taiwan (65.5%). On contrary, the study that was done in Poland revealed that training helped to increase compliance levels to food processors from 56% to 77% (12). Studies done in Kenya and Poland found lack of training was a major hindrance for good performance of food safety management practices among small scale food processors (40). Several studies proven high compliance to food processors is highly influenced by training. For instance, in India, Sri Lanka, USA, Taiwan and in developing countries, lack of training was the major barrier to improvement of quality management systems in food industries (18,26,40,42,43).

This study also found that, none of the millers who took initiative to train his employees or himself using his own resources. Majority were trained by TFDA and some by World Vision. The attitude of small scale maize millers not to be ready to use their own resources for learning GMP implies that, they did not recognize the importance of training for quality improvement. Furthermore, none of them had employed qualified personnel to supervise the production despite being the requirement for premises registration. This implies that, they might provide false information to the regulatory authority that they had employed qualified personnel. Failure to employ qualified personnel might be caused by low financial capacity to pay them, negative perceptions, lack of motivation to compliance, low punishment in case of non-conformances and lack of proper channel to link with technical experts.

Practical implementation of Good Manufacturing Practices in small scale maize milling factories requires adequate knowledge of millers on the GMP requirements (46). Therefore, it is supposed to be prioritized by millers and they need to have internal arrangement for regular training without depending much on TFDA guidance, having management commitment, employ permanent workers, improve working conditions and devoting their time to quality improvement.

### **5.3.3 Ability to meet compliance cost**

This study found that nearly half of the millers were able to meet the compliance cost. However, ability of millers to meet compliance cost did not influence GMP compliance. This might be due to lack of willingness to comply among small scale maize millers who were able to meet compliance cost. That was evidenced in the study done in Serbia which found that ability to afford cost among food manufactures without willingness, high compliance cannot be realized (48). Furthermore, it might be due to low level of education of millers and due to lack of technical expertises that could trigger compliance. Millers might be more likely to comply to GMP if the benefits of compliance would outweigh the compliance cost. Studies shows that manufacturers of developing countries are willing to comply if compliance is cost effective (9,15).

Studies done elsewhere have also found that ability of small scale food manufactures to meet compliance cost has not been significantly associated with GMP compliance. For instance, in UK, only 16% of the small scale food processors had ability to meet cost of compliance to food safety regulations were compliant (37). Likewise, a study done in developing countries revealed low compliance among processors who were able to afford the costs. On contrary, a study that was done in Sri Lanka and India found compliance cost to influence adherence with regulatory requirements among small scale food manufacturers (18, 40).TFDA should find a way to motivate millers who have ability to meet compliance cost to comply with GMP and encourage them to employ qualified personell (44).

### **5.3.4 Guidance from Tanzania Food and Drugs Authority**

This study found that lack of guidance from TFDA was the predictor of the GMP compliance. Millers who were supported within the past 12 months by TFDA on how to comply with GMP requirements found to be more likely to comply with GMP requirements than those who were not supported. Failure of TFDA to effective provide guidance to millers partly proved the allegation that TFDA was among of the government institution which found not to be effective to support small scale food manufacturers to comply with quality and safety requirements

(41). These findings align with the studies that were done in UK and Kenya which found small scale manufacturers who were not sufficiently guided by the government failed to adhere with the regulatory requirements (15,40).

Low compliance among processors who were not guided by TFDA might be due to high dependency of small scale maize flour processors on TFDA in their decision making process with regard to GMP compliance. This behaviour supposed to be discouraged because the principle of food safety management systems is that manufacturer is primarily responsible for quality improvement in their establishments. Since they were not technical capacitated, the government could help them to adopt the approaches that were used by food manufacturers in many countries of the world such as Zimbabwe, Serbia and UK. They hired external consultants to help them to improve their food safety management systems and minimize their dependency to regulatory bodies (48).

### **5.3.5 Faced legal action for going against GMP**

This study found quarter of the millers where punished for failure to comply with GMP in the past 12 months despite the fact that almost all found not adhere to majority of GMP requirements. Furthermore, this study found facing legal actions among millers did not influence compliance. This might be caused by low level of punishment (fined) given to majority of those who faced legal actions and inconsistency in decision making.

Poor law enforcement in Tanzania is similar to many countries of the world including Sri Lanka. Also align with small scale food processors of China and Poland (11,19,27,40,11). The same was observed in enforcement of food fortification regulations, law penalties and inconsistency in decision making led to failure of implementation of that regulations in majority of processors in 12 low income countries (11).

This study advised TFDA to strengthen law enforcement to small scale maize millers of Ubungu and Kinondoni Districts because it is among of necessary mechanism for improving GMP compliance.

### **5.3.6 Premises ownership**

This study found majority of small scale maize millers used rented buildings. Millers who used rented buildings found to be less likely to comply with GMP requirements. Use of rented buildings was claimed to be among of the major challenges claimed by millers in the sense that they were not allowed to make any modification as per GMP requirements without getting permission from the owners.

Based on these findings, the behaviour of using rented buildings shall be discouraged. The government needed to capacitate millers financially so that they could be able to build their own facilities that would meet GMP requirements and make modification whenever deemed necessary.

## **5.4 Registered small scale millers' perceptions on GMP requirements**

### **5.4.1 Necessity of GMP requirements**

Compliance to GMP highly depends on the perceived benefits among food manufacturers (54). This study found that, majority of small scale maize millers perceived the benefits of GMP were production of safe food for human consumption. This implied that they were aware of the primarily goal of application of GMP in food industries. However, it was found GMP compliance was not influenced by millers' perception on necessity of GMP in milling industries. These results contradict with behavior theories which assume high probability of behaviour to occur among people with positive perceptions towards the behaviour. However, the findings might not reflect their true perception; it might be due to the reasons provided by food inspectors when they emphasized compliance during supervision or head GMP importance through media (information bias).

The findings of this study also were contrary to the study done in Sweden which found the main necessity of compliance is to increase sales and good relationship with customers rather than safety by majority of manufacturers (55). Different results were observed in the studies done in Sweden, Taiwan and Serbia which found high compliance among food processors

who perceived food safety regulations were necessary to be implemented in their industries (26,55).

Understanding the necessity of GMP alone cannot trigger compliance if other barriers to compliance among millers persist. Poor infrastructure systems, lack of motivation, lack of technical expertise, low education level, lack of sufficient guidance from regulatory Authority, low financial capacity and weak regulatory monitoring might influence low compliance level among small scale maize millers who knew the basic benefit of compliance.

#### **5.4.2 Complexity of GMP requirements**

This study found that millers who perceived that GMP requirements were difficult to be implemented were less likely to be GMP compliant. The most claimed difficult requirements were requirements for location, building, storage, water and laboratory analysis for quality control because of poor financial capacity, insufficient space, lack of technical capacity and use of rented buildings. Furthermore, the reasons provided by the millers, perception on difficultness of GMP requirements could also be explained by the findings of the study done in Malaysia in 2016 which assessed knowledge, attitudes and practices on GMP among food handlers. According to that study, handlers who had inadequate GMP knowledge and low levels of education found GMP requirements difficult to be implemented(56).

Low GMP compliance was also realized among food manufactures who perceived GMP requirements were difficult to be implemented in studies done in Sri Lanka and in low and middle income countries.(40). Also another study found low compliance to fortification regulations among processors who perceived implementation of the regulations was difficult (11).

#### **5.5 Factors that affect GMP supervision by the regulatory Authority**

Results show TFDA-Eastern Zone Office faced huge human and financial resources deficit. The situation was worsened due to rapidly emerged small scale food enterprises beyond their capacity to regulate them in terms of human and technical capacity. Without adequate human and financial resources, the problem of low GMP compliance will persist because their

regulatory capabilities will be stagnant and even deteriorating (15). Insufficient human and financial resources in regulatory authorities had also been found to be the problem in low and middle income countries (1) and in Poland (11).

On the other hand, technical capacity was not found as a barrier to effective monitoring and supervision activities by TFDA. However, TFDA must ensure that trained and experienced inspectors are maintained by using motivational approaches such as increasing their salaries, recognition and incentives. That must be accompanied by employing more inspectors so as to relieve the present inspectors from overwhelming (15). On the contrary to this study, another study which assessed regulatory monitoring of fortified foods revealed technical capacity was the problem facing regulatory authorities in developing countries (1). Also, a study done in Poland revealed the same among food inspectors in regulatory authorities (11).

This study also found the effort made to help millers of Ubungo and Kinondoni districts to comply with GMP requirements was not sufficient since majority did not comply with GMP requirements and majority were not inspected in the last 12 months. Provision of training programs and providing directives on what should be done particularly during inspection was not satisfactory. TFDA was supposed to prioritize interventions that will encourage small scale maize millers to identify their own problem without depending on inspectors' directives.

### **5.6 Study limitation**

- Strategic response bias from interviewee because researchers were together with the wards Health Officers. There was a possibility of their response not to reflect the reality.
- Interviewed inspectors at the Tanzania Food and Drugs Authority-EZO were familiar with the principal researcher. Therefore they might be bias in their responses.
- Compliance level was estimated at single point in time (cross sectional) therefore might reduce reliability of the data.
- Compliance data were collected by observations checklist therefore; there might be errors due to personal judgements.
- Results cannot be generalized to the general population because the sample was small.

### **5.7 Strength of the study**

- Use of standard data collection tool to measure GMP compliance which was TFDA GMP observation checklist.
- The study managed to reach all small scale maize millers who met inclusion criteria for the study.



## CHAPTER SIX

### 6.0 CONCLUSION AND RECOMMENDATIONS

#### 6.1 Conclusions

**From this study the following conclusions are made;**

1. Proportion of compliance to GMP requirements among registered small scale maize milling industries of Ubungo and Kinondoni Districts was low (21.9%).
2. The main determinants of GMP compliance were level education of the millers, guidance from TFDA within the past 12 months and building ownership.
3. GMP requirements were perceived necessary in maize milling industries by small scale maize millers.
4. GMP requirements were perceived difficult to be implemented mainly because of low financial capacity, lack of technical capacity, insufficient space to effect changes, use of cheap labour and rented buildings.
5. Factor that affect GMP supervision by TFDA in Ubungo and Kinondoni Districts were low financial and human resources.

#### 6.2 Recommendations

1. Small scale maize millers of Ubungo and Kinondoni Districts should employ qualified personnel for supervision; have internal arrangements for training and self-regulatory mechanism so as to minimize high dependency on guidance from TFDA; avoid use of rented building and shift to industrial areas so as to comply with GMP requirements.
2. Tanzania Food and Drugs Authority should increase the budget for supervision activities; employ sufficient number of food inspectors; translate GMP guidelines and relevant laws into Kiswahili language and strengthening law enforcement and capacity building to all small scale maize millers of Ubungo and Kinondoni Districts so as to increase proportion of GMP compliance in their factories.

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## APPENDICES

### Appendix I: English version questionnaire for the owner of the milling industry

Questionnaire to find out millers factors that affect GMP implementation among registered small maize millers and their opinion in Ubungo and Kinondoni districts

#### OFFICIAL USE:

Name of District..... Questionnaire No.....

Name of Ward..... Sex of the respondent.....

Name of interviewer..... Date of interview .....

<b>SECTION 1: SOCIAL DEMOGRAPHIC INFORMATION OF THE MILLER</b>		
<b>QUESTION</b>		<b>RESPONSE</b>
1.	How old are you? ( <i>age in years</i> )	.....
2.	Building ownership ( <i>Tick appropriate</i> )	1. Rented 2. Not rented
3.	What is your level of education? ( <i>Tick appropriate</i> )	1. No formal education 2. Primary education 3. Secondary education 4. Higher education (specify).....
4.	Have you employed a qualified person responsible for quality and safety assurance	1. Yes 2. No
5.	How many years of experience do you have in milling business ( <i>Mention</i> )	.....



6.	What is your position in this business ( <i>Tick appropriate</i> )	1. Owner 2. Most knowledgeable person
7.	Number of employees ( <i>Mention</i> )	.....
<b>SECTION 2: AWARENESS ON GMP</b>		
8.	Are you aware of GMP in milling industries? ( <i>Tick appropriate</i> )	1. Yes 2. No
9.	If yes, where did you heard about GMP? ( <i>Tick appropriate</i> )	1. At the college 2. Through media 3. FromTFDA 4. Others ( <i>Mention</i> ) .....
<b>SECTION 3: TRAINING ON GMP</b>		
10.	Have you trained on GMP? ( <i>Tick appropriate</i> )	1. Yes 2. No
11.	How many staff that were trained on GMP? ( <i>Tick appropriate</i> )	.....
12.	If yes who trained them? ( <i>Tick appropriate</i> )	1.TFDA 2.Elsewhere ( <i>Mention</i> ) .....
13.	How many times they were trained? ( <i>Tick appropriate</i> )	1. Once 2. Two 3. Three 4. More than three
14.	Which aspect of GMP requirements they were trained? ( <i>Tick all appropriate</i> )	1. All 2. Some( <i>Mention</i> ) ..... .....

		<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
15.	<p>Is also the milling supervisor trained on GMP? <i>(Tick all appropriate)</i></p>	<p>1. Yes</p> <p>2. No</p>
<p><b>SECTION 4 ABILITY TO MEET COMPLIANCE COST</b></p>		
16.	<p>Can you manage to afford the cost of all GMP requirements?</p>	<p>1. Yes</p> <p>2. No</p>
17.	<p>If not which GMP requirement do you fully afford the cost? <i>(Tick all appropriate)</i></p>	<p>1. Requirements for location</p> <p>2. Requirements for building</p> <p>3. Requirements for water</p> <p>4. Requirements for sanitation</p> <p>5. Requirements for staff hygiene</p> <p>6. Requirements for storage of raw material and products</p> <p>7. Requirements for quality testing</p> <p>8. Requirements for maize flour processing</p> <p>9. Requirements for labeling</p> <p>10. Requirements for records</p> <p>11. None</p>
<p><b>SECTION 5 SUPPORT/GUIDANCE FROM TFDA</b></p>		
18.	<p>Have you ever inspected by TFDA in the past 12 months?</p>	<p>1. Yes</p> <p>2. No</p>
19.	<p>If yes to question 19, how many times in the past 12</p>	<p>a. Once</p>

	months you have been inspected?	<ul style="list-style-type: none"> <li>b. Twice</li> <li>c. Three times</li> <li>d. Four times</li> <li>e. More than four times</li> </ul>
20.	After being inspected, what they normally recommend you to do?	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
21.	Do you receive any guidance for quality improvement from TFDA in the past 12 months? <i>(Tick appropriate)</i>	<ul style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ul>
22.	How many times in a year you have received such guidance? <i>(Tick appropriate)</i>	<ul style="list-style-type: none"> <li>1. One time per year</li> <li>2. Two time in a year</li> <li>3. 3 times in a year</li> <li>4. More than 3 times</li> </ul>
<b>SECTION 6: ASSESSMENT OF HOW MAIZE QUALITY IS CHECKED BY MILLERS FROM SELLERS</b>		
23.	Where do you normally source maize stock? <i>(Tick appropriate)</i>	<ul style="list-style-type: none"> <li>1. From retailers</li> <li>2. From farmers</li> <li>3. Other sources .....</li> <li>.....</li> <li>.....</li> </ul>
24.	How do you measure the quality of the maize stock before accepting to be used in processing? <i>(Tick appropriate)</i>	<ul style="list-style-type: none"> <li>1. Visual assessment</li> <li>2. Performing laboratory analysis</li> </ul>

		3. Both 4. Others ..... 5. ....
25.	If it is visual assessment, tell me what are your selection criteria? ( <i>Mention</i> )	..... ..... .....
26.	If laboratory test is performed, which test are do you analyze ( <i>Mention</i> )	..... ..... .....
27.	Where do you analyze the samples ( <i>Tick appropriate</i> )	1. TFDA 2. In the factory laboratory 3. Others (mention).....
28.	Registration of at least one product	1. Yes 2. No
29.	What are the challenges encountered in selection of proper maize for processing of maize flour ( <i>Mention</i> )	..... ..... ..... .....
<b>SECTION 7: NUMBER OF FACED LEGAL ACTIONS WITHIN 12 MONTHS</b>		
30.	Have you faced any legal action from TFDA in case of none compliance within the last 12 months? ( <i>Tick appropriate</i> )	1. Yes 2. No
31.	If yes, how many times within last 12 months? ( <i>Tick appropriate</i> )	1. One time per year 2. Two time in a year 3. 3 times in a year 4. More than 3 times
32.	Which offence that you committed? ( <i>Mention</i> )	..... .....

		..... ..... .....
33.	What was the legal actions taken? <i>(tick all appropriately)</i>	1. Closure of the premises 2. Stopped to sell the produced flour 3. Ban 4. Penalties 5. Imprisonment
<b>SECTION 8: REGISTERED SMALL SCALE MILLERS OPINION ON GMP REQUIREMENTS</b>		
34.	Do you think GMP is necessary in milling industries? <i>(Tick appropriate)</i>	1. Yes 2. No
35.	Give reasons for the above ..... ..... .....	
36.	Are GMP requirements difficult to be implemented? <i>(Tick where appropriate)</i>	1. Yes 2. No
37.	If yes, which GMP requirements are difficult to be implemented? <i>(Mention)</i>	..... ..... ..... ..... ..... .....

38.	Why are they difficult to be implemented? ..... ..... ..... ..... .....
39.	What do you think can be done by TFDA that could be of help for you to abide with GMP requirements? ..... ..... ..... ..... .....
40.	What are other challenges that you are facing towards effort to GMP compliance? ..... ..... .....

## Appendix II: Swahili version of the questionnaire for owner of the milling industry

### DODOSO

Dodoso kujua vitu vinavyohusiana na kukidhi viwango vya uzalishaji bora wa unga wa mahindi uliofungashwa kwenye viwanda vidogo vya unga wa mahindi vilivyosajiliwa na Mamlaka ya Chakual na Dawa pamoja na maoni ya wazalishaji katika wilaya ya Ubungo na Kinondoni.

### KWA MATUMIZI YA OFISI TU

Wilaya ..... Na. ya Dodoso.....

Jina la kata ..... Jina la mtaa.....

Jina la anayehoji ..... Tarehe ya mahojiano.....

SEHEMU YA 1: TAARIFA ZA AWALI		
MASWALI		MAJIBU
1	Una umri gani? (miaka)	.....
2	Kiwango cha elimu? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Sina elimu 2. Elimu ya msingi 3. Elimu ya sekondari 4. Elimu ya juu (Eleza).....
3.	Taja taaluma yako?	.....

4.	Una uzoefu wa miaka mingapi katika uzalishaji wa unga?	.....
5.	Wadhifa	1. Mmiliki 2. Mtu mwenye uzoefu na uelewa zaidi
6.	Idadi ya wafanyakazi ( <i>Taja</i> )	.....
7.	Umeajiri mtu aliyesomea utaalamu wa kuhakikisha bidhaa inayozalishwa ni bora na salama ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Yes 2. No
8.	Umiliki wa jengo ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Nimepanga 2. Namiliki mwenyewe
<b>SECTION 2: UELEWA WA MAHITAJI YA KUKIDHI VIGEZO VYA UZALISHAJI BORA WA CHAKULA</b>		
9.	Unafahamu juu ya uwepo wa mahitaji ya kukidhi vigezo vya uzalishaji bora wa unga wa mahindi? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Ndio 2. Hapana
10.	Kama jibu ni ndio, ulisikia wapi?	1. Chuoni 2. Kwenye vyombo vya habari 3. Kupitia wakaguzi wa TFDA 4. Kwingine.....



<b>SEHEMU YA 3: MAFUNZO YA UZALISHAJI BORA WA CHAKULA</b>		
11.	Je umeshawahi kupata mafunzo juu ya uzalishaji bora wa unga wa mahindi? <i>(weka alama ya vema kwenye jibu husika)</i>	1. Ndio 2. Hapana
12.	Wafanyakazi wangapi wamepata mafunzo juu ya uzalishaji bora wa unga wa mahindi? <i>(weka alama ya vema kwenye jibu husika)</i>	1. Hakuna 2. Wote 3. Mmoja 4. Wawili 5. Watatu 6. Zaidi ya watatu
13.	Kama jibu ni ndio, eleza walipata mafunzo hayo kutoka wapi? <i>(weka alama ya vema kwenye jibu husika)</i>	1. TFDA 2. Kwingine (Taja) .....
14.	Walipata mafunzo hayo mara ngapi? <i>(weka alama ya vema kwenye jibu husika)</i>	5. Mara moja 6. Maa mbili 7. Mara tatu 8. Zaidi ya mara tatu
15.	Walifundishwa juu ya nini? <i>(weka alama ya vema kwenye jibu husika)</i>	1. Mahitaji yote ya uzalishaji bora 2. Mahitaji baadhi (Taja)
16.	Anayesimamia uzalishaji pia amepata mafunzo ya namna bora ya kuzalisha unga salama kwa afya za walaji? <i>(weka alama ya vema kwenye jibu husika)</i>	a. Ndiyo b. Hapana
<b>SEHEMU YA 4: UWEZO WA KUKIDHI GHARAMA</b>		
17.	Je unaweza kulipia gharama zinazohitajika ili uweze kukidhi mahitaji yote ya uzalishaji bora wa unga wa mahindi?	1. Ndio 2. hapana

	<i>(weka alama ya vema kwenye jibu husika)</i>	
18.	Kama jibu ni hapana, mahitaji yapi unaweza kulipia? <i>(weka alama ya vema kwenye jibu husika)</i>	<ol style="list-style-type: none"> <li>1. Mahitaji ya eneo la kiwanda linalofaa</li> <li>2. Mahitaji ya ingo.</li> <li>3. Mahitaji ya maji</li> <li>4. Mahitaji ya usafi wa mazingira</li> <li>5. Mahitaji ya usafi wa wafanyakazi</li> <li>6. Mahitaji ya kuhifadhi mahindi na unga</li> <li>7. Mahitaji ya kupima sampuli</li> <li>8. Namna ya kuzalisha unga na kupaki</li> <li>9. Kuandika taarifa zinazotakiwa kwenye lebo</li> <li>10. Mahitaji la kutunza kumbukumbu</li> <li>11. Hakuna ninaloweza kulipia</li> </ol>
<b>SEHEMU YA 5: MSAADA KUTOKA TFDA</b>		
19.	Ulishawahi kukaguliwa na Mamlaka ya chakula na dawa kwa kipindi cha miezi kumi na mbili iliyopita? <i>(weka alama ya vema kwenye jibu husika)</i>	<ol style="list-style-type: none"> <li>1. Ndio</li> <li>2. Hapana</li> </ol>
20.	Kama jibu ni ndiyo, mara ngapi kwa mwaka? <i>(weka alama ya vema kwenye jibu husika)</i>	<ol style="list-style-type: none"> <li>1. Mara moja</li> <li>2. Mara mbili</li> <li>3. Mara tatu</li> <li>4. Mara nne</li> <li>5. Zaidi ya mara nne</li> </ol>
21.	Baada ya kukaguliwa, huwa wanakushauri kufanya nini? <i>(Taja)</i>	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

		.....
22.	Je unapata mwongozo kutoka kwa wakaguzi wa TFDA kwa kipindi cha miezi 12 iliyopita? ( <i>weka alama ya vema kwenye jibu husika</i> )	<ol style="list-style-type: none"> <li>1. Ndio</li> <li>2. Hapana</li> </ol>
23.	Ulipata msaada huo mara ngapi? ( <i>weka alama ya vema kwenye jibu husika</i> )	<ol style="list-style-type: none"> <li>1. Mara moja kwa mwaka</li> <li>2. Mara mbili kwa mwaka</li> <li>3. Mara tatu kwa mwaka</li> <li>4. Zaidi ya mara tatu</li> </ol>
<b>SEHEMU YA 6: TATHMINI YA NAMNA WAZALISHAJI WANAVYOPIMA NA KUJUA UBORA WA MAHINDI KUTOKA KWA WAUZAJI</b>		
24.	Huwa unanunua kwa nani mahindi kwa ajili ya uzalishaji unga? ( <i>weka alama ya vema kwenye jibu husika</i> )	<ol style="list-style-type: none"> <li>1. Kutoka kwa wafanyabiashara</li> <li>2. Kutoka kwa wakulima</li> <li>3. Kwengine (<i>taja</i>)</li> </ol> <p>.....</p> <p>.....</p>
25.	Unapima vipi ubora wa mahindi kutoka kwa wauzaji kabla haujanunua kwa ajili ya kuzalisha unga? ( <i>weka alama ya vema kwenye jibu husika</i> )	<ol style="list-style-type: none"> <li>1. Kwa macho</li> <li>2. Kupima sampuli maabara</li> <li>3. Kwa macho na kupima maabara</li> <li>4. Namna nyinge (<i>Taja</i>)</li> </ol> <p>.....</p> <p>.....</p>
26.	Kama ni kwa macho, niambie unatumia vigezo gani? ( <i>Taja</i> )	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

27.	Kama unapima maabara, huwa unapima nini? ( <i>Taja</i> )	..... .....
28.	Unapimia wapi sampuli? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Mamlaka ya chakula na dawa 2. Kwenye maabara ya kiwanda 3. Sehemu nyingine (Taja).....
29.	Umeshasajili bidhaa angalau moja? ( <i>look on the evidence of the certificate</i> )	1.Yes 2.No
30.	Changamoto gani nyingine unakabiliana nazo kutoka kwa wauzaji zinazohusiana na ubora wa mahindi? ( <i>Taja</i> )	..... ..... .....
<b>SEHEMU YA 7: KUCHUKULIWA HATUA ZA KISHERIA NDANI YA KIPINDI CHA MWAKA MMOJA</b>		
31.	Je umewahi kuchukuliwa hatua zozote za kisheria na wataalam wa TFDA ndani ya kipindi cha miezi 12 iliyopita? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Ndio 2. Hapana
32.	Kama jibu ni ndio mara ngapi? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Mara moja kwa mwaka 2. Mara mbili kwa mwaka 3. Mara tatu kwa mwaka 4. Zaidi ya mara tatu
33.	Ulifanya kosa gani? ( <i>Taja</i> )	..... .....
34.	Ni hatua gani uliyochukuliwa? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Kuzuiliwa kuendelea kuzalishwa 2. Kuzuliwa kuuza unga uliozalisha 3. Kuteketezwa kwa unga uliozalisha 4. Tozo 5. Kifungo

<b>SECTION 8: MAONI JUU YA MAHITAJI YA KUKIDHI VIGEZO VYA UZALISHAJI BORA WA CHAKULA</b>		
35.	Je unafikiri ni muhimu kukidhi vigezo vya uzalishaji bora wa chakula? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Ndio 2. Hapana
36.	Toa sababu ya jibu ulilochagua kwenye swali 25 ..... .....	
37.	Je vigezo vya uzalishaji bora wa chakula ni vigumu kutekelezwa? ( <i>weka alama ya vema kwenye jibu husika</i> )	1. Ndio 2. Hapana
38.	Kama ndio, niambie ni vigezo gani unavyoona ni vigumu kutekeleza? ( <i>Taja</i> )	..... .....
39.	Kwa nini vigezo hivyo ulivyochagua ni vigumu kutekeleza? ..... ..... ..... .....	
40.	Unafikiri Mamlaka ya Chakula na Dawa ikusaidie nini ili uweze kukidhi matakwa yote ya uzajishaji bora wa unga wa mahindi? ..... ..... .....	
41.	Eleza changamoto nyingine unazokabiliana nazo zinazokuzuia katika harakati za kukidhi vigezo vya uzalishaji bora wa unga wa mahindi? ..... ..... .....	

**Appendix III: English version of the interview guide for food inspectors at TFDA  
Eastern Zone Office**

Questionnaire to find out factors that affect GMP supervision by TFDA in Ubungo and Kinondoni districts

**OFFICIAL USE:**

Name of the Zone..... Questionnaire No.....

Name of interviewer..... Date of interview .....

Age of the interviewee .....

**A: Technical resource capacity**

Q1: What is your level of education (including professional)  
.....

Q2: How many years of experience in inspection/supervision activities in small scale maize flour milling? .....

Q3: Are you all having adequate technical capacity for inspection activities?  
.....  
.....  
.....  
.....

Q4: Do you have onjob training for capacity building?

.....  
.....  
.....  
.....

Q5: Is your employer supportive for further training?

.....  
.....  
.....  
.....

**B. Human resource capacity**

Q6: How many food inspectors available for inspection activities in this Zone? .....

Q7: In your opinion, do you think you are sufficient? (*circle where appropriate*)

.....

Q8: Give reasons for your answer in Q4

.....  
.....  
.....

**C. Financial capacity**

Q9: What is your opinion on the budget allocated for supervision activities, is it sufficient?

.....

Q10: Give reasons for your answer in Q6

.....  
.....  
.....  
.....

Q11: What effort has been done to make small scale maize millers in Ubungo and Kinondoni Districts to comply with TFDA regulatory requirements?

.....  
.....  
.....

Q12: Is the effort made sufficient? .....

Q13: Give reason for your answer

.....  
.....  
.....  
.....

Q14: What are the challenges your facing on the effort to make small scale maize millers in Ubungo and Kinondoni Districts to comply with regulatory requirements?.....

.....  
.....  
.....  
.....

Q15: What do you think could be the reasons for low compliance to regulatory requirements in small scale maize milling industries?

.....  
.....  
.....  
.....

Q16: Any other opinion

.....  
.....  
.....



**Appendix IV: Kiswahili version of the interview guide for food inspectors at TFDA  
Eastern Zone Office**

**DODOSO**

Dodoso kubaini mambo yanayoathiri usimamiaji wa vigezo vya kukidhi vya uzalishaji bora wa unga na Mamlaka ya Chakula na Dawa katika wilaya za Ubungo na Kinondoni

**Kwa matumizi ya ofisi tu:** Dodoso .....

Jina la kata .....

Jina la mtaa.....

Jina la anayehoji .....

Tarehe ya mahojiano.....

Jinsia ya mhojiwa.....

Umri wa anayehojiwa.....

**A: Uwezo wa kitaaluma**

1. Taja kiwango chako cha juu cha elimu (ikiwa ni pamoja na taaluma yako)

.....

2. Una uzoefu wa miaka mingapi katika kazi za ukaguzi katika viwanda vidogo vya kuzalisha unga na kufungasha? .....

3. Wakaguzi wa kanda hii wote mna uwezo wa kitaalamu wa kutoka katika kazi za ukaguzi?

.....  
.....  
.....  
.....

4. Mna utaratibu wa mafunzo ya ndani?

.....  
.....  
.....  
.....

5. Mwajili wenu anawasaidia kujiendeleza kitaaluma?

.....  
.....  
.....  
.....

**B. Uwepo wa wakaguzi wa kutosha**

6. Kuna wakaguzi wangapi katika kanda hii? .....

7. Unafikiri wanatosha?

.....

8. Toa sababu kwa jibu lako

.....  
.....

**C. Uwezo wa kifedha**

9. Una maoni gani juu ya fedha inayotengwa kwa ajili ya kusimamia uzingatiwaji wa vigezo vya uzalishaji salama wa chakula? Inatosha?

.....

10. Toa sababu kwa jibu lako

.....

.....

11. Mmefanya juhudi gani kuwasaidia wazalishaji wadogo wa unga wa mahindi wanaozalisha na kufungasha katika wilaya ya Ubungo na Kinondoni?

.....

.....

12. Unafikiri juhudi hizo zimetosha?

.....

13. Toa sababu kwa jibu lako

.....

.....

14. Mnakutana na changamoto gani katika juhudi za kuwasaidia wazalishaji wadogo wa unga wa mahindi wanaozalisha na kufungasha katika wilaya ya Ubungo na Kinondoni ili waweze kuzingatia vigezo vya uzalishaji bora wa unga?

.....

.....

Q15. Unafikiri kwa nini wengi wanashindwa kukidhi vigezo hivyo?

.....

.....

Q16. Maoni mengine

.....

.....

**Appendix V: Good manufacturing practices observation checklist**

<b>REQUIREMENTS</b>	<b>POINTS ALLOCATED</b>	<b>POINTS SCORED</b>
<b>1. LOCATION / SITING</b>		
-Within industrial area	1	
- Free from sources of contamination	2	
- Accessible by road	2	
- Sound surface water drainage in place	2	
<b>2. BUILDING / CONSTRUCTION</b>		
- Of Permanent material and	1.5	
- Of good state of repair	1.5	
- Proper adequate air ventilation provided to prevent dust explosion	5	
- Floor finish is hard	0.5	
- Floor finish smooth	0.5	
- Floor finish is non-absorbent	0.5	
No accumulation of grime oils or dust on the floor	1	
- Room provides adequate area to accommodate activities carried on	3	
- Good floor drainage with no stagnant water	1	
-No stagnant water on the floor	1	
- Walls internally plastered, and or painted	3	
- Roofing or ceiling has no leakage	4	
<b>3. WATER SUPPLY</b>		
- Presence of draining water (Municipal or private) potable	1	

and available all the time		
- Water supply is adequate in volume and Pressure	1	
<b>4. RAW MATERIALS</b>		
- Raw materials stored properly	5	
- *Adequate ventilation	4	
- Temperature and humidity condition maintained	4	
- *Maize grains in sound condition	5	
- *Pesticides properly stored and labeled	4	
- Packaging material is suitable and of food grade	4	
<b>5. FOOD EQUIPMENT &amp; PROCESS</b>		
- Food contact surfaces be clean	3	
- Non food contact surfaces be well cleaned	2	
-Milling process is adequate to prevent contamination	4	
- Proper insect and rodent control along the processing line up to the storage of processed products	2	
- Food products properly packaged	2	
- Food products properly labeled	2	
<b>6. SANITATION &amp; STAFF HYGIENE</b>		
Presence of toilets	2	
- *Sufficient number of toilets available	2	
*Presence of hand washing facilities provided	2	
-Clean toilets	2	
- Proper sewage and waste water disposal	3	
-Proper drainage facilities	1.5	
- Employees medically examined on first appointment	1	
- Employees medically examined after every six months	1	
- Employees provided with clean protective clothing	3	

- Cleaning schedules & methods recorded	2	
- Dressing rooms provided	1	
-Dressing rooms kept clean	1	
<b>7. RECORDS</b>		
- Quality control test records of raw materials & finished products.	2	
Medical examination records	2	
Cleaning disinfection/ disinfestations	2	
<b>8. GRAND TOTAL SCORE (OUT OF)</b>	<b>100</b>	

*\*These are critical defects*

**Appendix VI: Informed Consent for the owner of the small scale milling industries**

ID NO: .....

**Introduction**

Hello! My name is Martina Lyimo, a student of Masters of Public Health at Muhimbili University of Health and Allied Sciences (MUHAS). On behalf of Muhimbili University of Health and Allied Sciences (MUHAS), I am conducting a research on GMP compliance and associated factors in small scale maize milling industries registered by TFDA in Ubungo and Kinondoni districts as part of my training.

**Purpose of the study**

Information on the proportion of GMP compliance in food industries is crucial for risk management and surveillance purposes. However, such information is not available for almost all food industries in Tanzania including small scale maize millers. Therefore, this study aims to provide information on the proportion of GMP compliance and the associated factors in small scale maize milling industries registered by TFDA in Ubungo and Kinondoni Districts. The findings of this study will broaden knowledge in GMP compliance in food industries.

**Participation**

I would like you to participate in this study. You have been chosen to participate because I think you can provide valuable information related to GMP compliance in Ubungo and Kinondoni District. If you choose to participate you will be interviewed for about 15-20 minutes. The questions that you will be asked will be related to associated factors of GMP compliance and your opinion on GMP requirements. I will also observe your premises to assess compliance to GMP requirements.

**Benefits**

If you agree to participate, it will be beneficial for improvement of your working conditions for the purpose of public health protection. This is because the findings of this study will help to know the magnitude of GMP compliance of registered small scale milling industries and factors associated in Ubungo and Kinondoni and can be used by the government in priority

setting during planning of educational interventions and supervision activities in the two districts.

**Risks**

I do not expect any harm to you as a result of participation in this study. Although some questions will be personal, but the information obtained from you and others will be used to generalized for the whole of Ubungo and Kinondoni Districts.

**Confidentiality**

All responses will be kept confidential and will be used only for the purpose of this study and will be private. No identification information will be collected from you during the interview, except your age, sex and education level.

**Right to refuse or withdraw**

Participation to this study is voluntary. You may decide to participate or not to. No measure will be taken upon your refusal to participate if you decided not to. You are free not to answer any question or any part of the discussion.

**Whom to Contact**

In case of any question or query concerning this study, please contact the principal investigator, Ms. Martina John Lyimo (MPH) from MUHAS, P. O. BOX 65001, Dar es Salaam, mobile number 0712 580 944. If you have any question about your rights as a participant you may contact Dr. Joyce Masalu, Chairperson of the research and Publications Committee, MUHAS. P.O. Box 65001, Dar es Salaam-Tanzania, Tel +2552150302-6)

I ..... have read the contents of this form and understand and my questions have been adequately answered. I agree to participate in this study.

Signature of participant..... Date.....

Signature of researcher ..... Date.....



## **Appendix VII: Fomu ya ridhaa kwa wamiliki wa viwanda vidogo vya unga wa mahindi**

**Namba ya utambulisho.....**

### **Utambulisho**

Habari, naitwa Martina John Lyimo, ni mwanafunzi wa shahada ya uzamili ya Afya ya Jamii katika chuo cha Afya na Sayansi ya Jamii Mhimbili. Katika sehemu ya mafunzo yangu ninafanya utafiti ili kujua ni kwa kiasi gani Njia Bora za Uzalishaji wa Chakula zinafuatwa na wazalishaji wadogo wa unga wanaofungasha ambao wamesajiliwa na Mamlaka ya Chakula na Dawa.

### **Madhumuni ya utafiti**

Taarifa juu ya namna Njia Bora za Uzalishaji wa Chakula zinafuatwa na wazalishaji wadogo wa unga waliosajiliwa na Mamlaka ya Chakula na Dawa ni muhimu katika mipango ya ufuatiliaji na kupunguza uwezekano wa jamii yetu kupatwa na magonjwa yatokanayo na ulaji wa chakula. Hata hivyo, taarifa hizi hazipo kwenye viwanda mbalimbali vinavyozalisha chakula hapa nchini ikiwa ni pamoja na wazalishaji wadogo wa unga wa Mahindi. Kutokana na hali hii, utafiti huu umelenga kujua ni kwa kiasi gani njia hizi zinafuatwa na wazalishaji wadogo wa unga wanaofungasha ambao waliosajiliwa na Mamlaka ya Chakula na Dawa pamoja na kubaini mambo yanayopelekea uzingatiwaji wa kanuni hizo katika wilaya na Ubungo na Kinondoni. Matokeo ya utafiti huu yanaweza kutumika katika mipango ya miradi ya utoaji elimu na kuwawezesha wazalishaji hawa kuweza kuboresha ubora wa bidhaa zao .

### **Ushiriki**

Ningependa ushiriki katika utafiti huu kwa kuwa ninahisi unaweza kutoa taarifa zitakazoweza kufanikisha utafiti huu. Kama utakubali kushiriki utahojiwa/ au kupewa dodoso ujaze kwa muda wa dakika zisizozidi 15-20. Maswali utakayoulizwa yatahusiana na vitu vinavyopelekea kufuatwa au kutokufuatwa kwa Njia Bora za Uzalishaji wa unga wa mahindi na wazalishaji wadogo waliosajiliwa na Mamlaka ya Chakula na Dawa katika wilaya ya Ubungo na Kinondoni. Pia, nitaangalia mfumo wako wa uzalishaji ili kupima uzingatiaji wa njia hizo.

**Faida**

Ushiriki wako katika utafiti huu ni wa thamani, taarifa utakazozitoa zitasaidia kuboresha mfumo wako wa uzalishaji kwa ajili ya kulinda afya ya walaji. Hii ni kwa sababu matokeo ya utafiti huu yatabaini kujua kwa kiasi gani Njia bora na salama za Uzalishaji wa Chakula zinazingatiwa na wazalishaji wadogo wa unga pamoja na kubaini mambo yanayopelekea uzingatiwaji wa kanuni hizo ili njia ya kupunguza matatizo zichukuliwe na serikali kama zitabainika.

**Athari**

Sitarajii mshiriki kupata madhara ya aina yeyote kwa kuamua kushiriki kwake. Ingawa baadhi ya maswali ni binafsi, lakini matokeo ya utafiri huu yatakuwa ya jumla kwa washiriki wote wa wilaya za Ubungo na Kinondoni.

**Usiri**

Taarifa zitakazokusanywa ni siri na hakuna mtu yeyote atakayeambiwa ulichosema bali zitatumika kwa madhumuni ya utafiti huu tu. Hapatakuwa na utambulisho wa mshiriki kwenye dodoso, isipokuwa mwaka wa kuzaliwa, jinsi na kiwango cha elimu tu.

**Haki ya kukubali au kukataa kushiriki**

Ushiriki katika utafiti huu ni wa hiari. Unaweza kukubali kushiriki au kukataa. Hapatakuwa na adhabu yeyote itakayochukuliwa dhidi yako kama utaamua kukataa kushiriki. Pia jisikie uhuru kuokujibu swali ambalo hutapenda kulijibu.

**Mawasiliano**

Kama uatahitaji ufafanuzi zaidi juu ya utafiti huu, usisite kuwasiliana na Mtafiti Mkuu bi. Martina John Lyimo, mwanafunzi wa shahada ya Uzamili ya Afya ya Jamii katika chuo cha Afya na Sayansi ya Jamii, S. L. P 65001, Chuo kikuu cha Afay na Sayansi ya Jamii Mhimbili, Dar es Salaam au namba ya kiganjani 0712 580 944. Kama una swali juu ya stahili zako unaweza kuwasiliana na Prof. Mohamed Aboud, ambaye ni mwenyekiti wa kamati ya utafiti na uchapaji, S. L. P 65001, Chuo kikuu cha Afay na Sayansi ya Jamii Mhimbili, Dar es Salaam au simu namba +2552150302-6.

Mimi .....Nimesoma/nimesikia na kuelewa madhumuni ya utafiti huu na maswali yangu yamejibiwa ipasavyo. Hivyo, nimeridhia kwa hiari yangu kushiriki.

Saini ya mshiriki..... Tarehe.....

Saini ya mtafiti ..... Tarehe.....

**Appendix VIII: Informed Consent for food inspectors at TFDA Eastern Zone Office**

ID NO: .....

**Introduction**

Hello! My name is Martina Lyimo, a student of Masters of Public Health at Muhimbili University of Health and Allied Sciences (MUHAS). On behalf of Muhimbili University of Health and Allied Sciences (MUHAS), I am conducting a research on GMP compliance and associated factors in small scale maize milling industries registered by TFDA in Ubungo and Kinondoni districts as part of my training.

**Purpose of the study**

Information on the proportion of GMP compliance in food industries is crucial for risk management and surveillance purposes. However, such information is not available for almost all food industries in Tanzania including small scale maize millers. Therefore, this study aims to provide information on the proportion of GMP compliance and the associated factors in small scale maize milling industries registered by TFDA in Ubungo and Kinondoni Districts. The findings of this study will broaden knowledge in GMP compliance in food industries.

**Participation**

I would like you to participate in this study. You have been chosen to participate because I think you can provide valuable information related to GMP compliance in Ubungo and Kinondoni District. If you choose to participate you will be interviewed for about 15-30 minutes. The questions that you will be asked will be related to TFDA factors that affect GMP compliance in small scale maize milling industries in Kinondoni and Ubungo Districts.

**Benefits**

If you agree to participate, it will be beneficial for improvement of your working conditions for the purpose of public health protection. This is because the findings of this study will help to know the magnitude of GMP compliance of registered small scale milling industries and factors associated in Ubungo and Kinondoni and can be used by the government in priority

setting during planning of educational interventions and supervision activities in the two districts.

**Risks**

I do not expect any harm to you as a result of participation in this study. Although some questions will be personal, but the information obtained from you and others will be used to generalized for the whole of Ubungo and Kinondoni Districts.

**Confidentiality**

All responses will be kept confidential and will be used only for the purpose of this study and will be private. No identification information will be collected from you during the interview, except your age, sex and education level.

**Right to refuse or withdraw**

Participation to this study is voluntary. You may decide to participate or not to. No measure will be taken upon your refusal to participate if you decided not to. You are free not to answer any question or any part of the discussion.

**Whom to Contact**

In case of any question or query concerning this study, please contact the principal investigator, Ms. Martina John Lyimo (MPH) from MUHAS, P. O. BOX 65001, Dar es Salaam, mobile number 0712 580 944. If you have any question about your rights as a participant you may contact Dr. Joyce Masalu, Chairperson of the research and Publications Committee, MUHAS. P.O. Box 65001, Dar es Salaam-Tanzania, Tel +2552150302-6)

I ..... have read the contents of this form and understand and my questions have been adequately answered. I agree to participate in this study.

Signature of participant..... Date.....

Signature of researcher ..... Date.....

**Appendix IX: Fomu ya ridhaa kwa wakaguzi wa chakula wa Mamlaka ya Chakula na Dawa kanda ya mashariki**

**Namba ya utambulisho.....**

**Utambulisho**

Habari, naitwa Martina John Lyimo, ni mwanafunzi wa shahada ya uzamili ya Afya ya Jamii katika chuo cha Afya na Sayansi ya Jamii Mhimbili. Katika sehemu ya mafunzo yangu ninafanya utafiti ili kujua ni kwa kiasi gani Njia Bora za Uzalishaji wa Chakula zinafuatwa na wazalishaji wadogo wa unga wanaofungasha ambao wamesajiliwa na Mamlaka ya Chakula na Dawa.

**Madhumuni ya utafiti**

Taarifa juu ya namna Njia Bora za Uzalishaji wa Chakula zinafuatwa na wazalishaji wadogo wa unga waliosajiliwa na Mamlaka ya Chakula na Dawa ni muhimu katika mipango ya ufuatiliaji na kupunguza uwezekano wa jamii yetu kupatwa na magonjwa yatokanayo na ulaji wa chakula. Hata hivyo, taarifa hizi hazipo kwenye viwanda mbalimbali vinavyozalisha chakula hapa nchini ikiwa ni pamoja na wazalishaji wadogo wa unga wa Mahindi. Kutokana na hali hii, utafiti huu umelenga kujua ni kwa kiasi gani njia hizi zinafuatwa na wazalishaji wadogo wa unga wanaofungasha ambao waliosajiliwa na Mamlaka ya Chakula na Dawa pamoja na kubaini mambo yanayopelekea uzingatiwaji wa kanuni hizo katika wilaya na Ubungo na Kinondoni. Matokeo ya utafiti huu yanaweza kutumika katika mipango ya miradi ya utoaji elimu na kuwawezesha wazalishaji hawa kuweza kuboresha ubora wa bidhaa zao .

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**Faida**

Ushiriki wako katika utafiti huu ni wa thamani, taarifa utakazozitoa zitasaidia kuboresha mfumo wako wa uzalishaji kwa ajili ya kulinda afya ya walaji. Hii ni kwa sababu matokeo ya utafiti huu yatabaini kujua kwa kiasi gani Njia bora na salama za Uzalishaji wa Chakula zinazingatiwa na wazalishaji wadogo wa unga pamoja na kubaini mambo yanayopelekea uzingatiwaji wa kanuni hizo ili njia ya kupunguza matatizo zichukuliwe na serikali kama zitabainika.

**Athari**

Sitarajii mshiriki kupata madhara ya aina yeyote kwa kuamua kushiriki kwake. Ingawa baadhi ya maswali ni binafsi, lakini matokeo ya utafiri huu yatakuwa ya jumla kwa washiriki wote wa wilaya za Ubungo na Kinondoni.

**Usiri**

Taarifa zitakazokusanywa ni siri na hakuna mtu yeyote atakayeambiwa ulichosema bali zitatumika kwa madhumuni ya utafiti huu tu. Hapatakuwa na utambulisho wa mshiriki kwenye dodoso, isipokuwa mwaka wa kuzaliwa, jinsi na kiwango cha elimu tu.

**Haki ya kukubali au kukataa kushiriki**

Ushiriki katika utafiti huu ni wa hiari. Unaweza kukubali kushiriki au kukataa. Hapatakuwa na adhabu yeyote itakayochukuliwa dhidi yako kama utaamua kukataa kushiriki. Pia jisikie uhuru kuokujibu swali ambalo hutapenda kulijibu.

**Mawasiliano**

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Mimi .....Nimesoma/nimesikia na kuelewa madhumuni ya utafiti huu na maswali yangu yamejibiwa ipasavyo. Hivyo, nimeridhia kwa hiari yangu kushiriki.

Saini ya mshiriki.....	Tarehe.....
Saini ya mtafiti .....	Tarehe.....