HAZARD ANALYSIS IN THE LOCALLY PROCESSED TOMATO SAUCES IN SELECTED COMPANIES IN IRINGA AND DAR-ES-SALAAM

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ABSTRACT

This dissertation aimed at analysing food hazards in the locally processed tomato sauces, assessing the adherence to food safety and quality control practices (FSQCPs), and investigating the microbial and pesticide residues contamination in the final product. The study was conducted in four companies in Iringa and Dar es Salaam, used structured questionnaires and observation checklist to collect data on the basic characteristics of firms, food hazards, and FSQCPs. Using laboratory tests, a total of forty samples of the final product collected from different batches of the companies under the study, were biologically and chemically investigated for the microbial and pesticide residues, respectively. The study reports three major findings. First, a detailed hazard analysis tool, indicating how each production process is undertaken along the entire production process chain of tomato sauce, for each company in the sample was developed and elaborated. Second, it was found that, on average, such companies adhered to majority of the components of FSQCPs. Third, for laboratory tests, the microbial load was found to be less than the detectable limits (that is, a limit of <100 CFU) and for chemical analysis there was no detectable residues of any pesticides. This finding suggests that tomato processing, to a greater extent, reduces the levels of both microbial load and pesticide residues that may be present in raw tomatoes sauce. Therefore, it is recommended that, tomato processing companies should continuously enhance the adoption of FSQCPs for strengthening product quality and productivity. Also, future studies may be extended to other food processing value chains in Tanzania.

DECLARATION

I, **RACHEL ATIENO MIRONDO**, do hereby declare to the Senate of Sokoine University of Agriculture that this dissertation is my own original work done within the period of registration and that it has neither been nor concurrently being submitted in any other institution.

__________________________________ _______________________

RACHEL ATIENO MIRONDO **Date**

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The above declaration is confirmed by;

__________________________________ _______________________

PROF. BENDANTUNGUKA P. TIISEKWA **Date**

(Supervisor)

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Any piece of scholarly work is a result of joint effort from God (the source of life) and fellow human being. This dissertation is not an exception. For this reason, therefore, I'm indebted to acknowledge the support received from those I can afford to.

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DEDICATION

To God

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ACRONYMS AND ABBREVIATIONS

BAM	Bacteriological Analytica Manual
CCPs	Critical Control Points
CFU	Colon Forming Units
CoA	Certificate of Analysis
FAO	Food and Agriculture Organization
FBD	Food Borne Diseases
FDA	Food and Drug Authority
FRAs	Food Regulatory Authorities
FSP	Food Safety Plan
FSQCPs	Food Safety and Quality Control Practices
GAP	Good Agricultural Practises
GC-MS	Gas Chromatography Mass Spectrometry
GHP	Good Hygienic Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Points
HAT	Hazard Analysis Table
ISO	International Organization for Standardization
MIT	Ministry of Trade and Industry
MT	Metric Tone
NBS	National Bureau of Statistics
QA	Quality Assurance
rcf	Relative Centrifugal Force
SIDO	Small Industry Development Organization

SSA	Sub Saharan Africa
TBS	Tanzania Bureau of Standards
TFDA	Tanzania Food and Drugs Authority
TIRDO	Tanzania Industrial Research and Development Organization
TPRI	Tanzania Pesticide Research Institute
TRA	Tanzania Revenue Authority
TVC	Total Viable Counts
URT	United Republic of Tanzania
WB	World Bank
WHO	World Health Organization

CHAPTER ONE

1. INTRODUCTION

1.1 Background Information

The United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO) suggest that food safety has increasigly become a major topic of public health concern worldwide (FAO and WHO, 2010). In part, this is because failure to keep food safe brings about food hazard, which is defined as the unacceptable levels of biological, chemical, or physical contaminants, which renders the food unfit for human consumption (Cusato *et al*., 2012; Ababio *et al*., 2016).

Potential adverse effects of food hazard are widespread, and practical evidence has shown that food hazard has had a devastating impact on the lives of consumers (Batt, 2016). Food hazard lowers consumer confidence in food manufacturing firms, diminishes profits, and affects the credibility of the food industry as a whole. Hence, the public health and food regulatory authorities of several countries have been looking for efficient ways to monitor food processing (Häsler *et al*., 2018).

According to Makiya and Rotondaro (2002), there are three major contaminants of food which describes food hazard. First, the growth and(or) survival of microorganisms in the food. The presence of such a biological activity in the food symbolizes the unacceptable biological food hazards. Second, the presence of pesticides residues, antibiotics, heavy metals, and cleaning products in food are classified as chemical food hazards. Third, physical food hazards include the presence of pieces of glass, metal, or other unwanted materials in the food.

Food hazards presence constitutes unsafe food, which is one of the leading causes of foodborne disease (FBD). Indeed, FBD is widespread in both developed and developing countries (WHO, 2015). For example, while about 48 million people are made sick, yearly average of 3,000 people lose their lives due to foodborne pathogens in the United States (Painter *et al*., 2013), in Africa, it is estimated that about 35% of epidemiological diseases in 2012 could be categorized as FBD (WHO, 2015). Unexpectedly, the magnitude of FBD in Tanzania is not accurately known due to the inexistence of a stable system for investigation of FBD, and that the majority of FBD cases go undiagnosed and unreported (TFDA, 2012). However, despite the lack of data, one cannot completely deny the incidences of FBD caused by consumption of unsafe food.

Identifying the possible food contaminants before they occur and defining the control measures to minimize food contamination in each step of food processing are among the pathways to implement an internationally accepted food safety management tool called hazard analysis and critical control points, commonly abbreviated as “HACCP” (Cullor, 1997). Unlike other approaches of food safety management, HACCP attempts to avoid hazards rather than seeking to inspect finished products for the effects of hazardous food hence conducting hazard analysis constitutes an important input into HACCP (Pierson and Corlett, 1992; Pierson, 2012).

Analyzing food hazards – this is the process of gathering and assessing data on hazards and conditions leading to their existence to decide which are significant for food safety (FAO and WHO, 1997) – particularly in food processing is crucial for accumulating empirical evidence to promote safety of tomato sauce. Evidently, for the past twelve years, production of fresh tomatoes has been in an increasing trend. For example, in 2008, production of fresh tomatoes in Tanzania stood at around 195,000 MT and that of Iringa region accounted for about 72% of the total national production of tomato and that around 87% of tomato produced in Iringa finds its market outside the region, particularly Dar es Salaam, which absorbs about 60% of tomato from Iringa (BCS and CSDI, 2009). In 2013, tomato production reached 423,323 MT (FAO, 2015) and it was estimated that the annual growth rate of production was 15%. However, given the installed capacity of processors in the country, only about 84,000 MT of fresh tomato are processed locally (WB, 2018).

To even out the availability of tomato throughout the year, tomato processing facilities have been installed in various regions of Tanzania, for example, Iringa and Dar es Salaam. Such facilities in Tanzania, as in other Eastern and Southern African countries, which are owned and operated by private entrepreneurs, range from small-, medium- and large-sized category of manufacturing firms consistent with the firm-size definition in Tanzania (URT, 2003; NBS and MITI, 2016). Tomato sauce is one of the major tomato products dealt with by such manufacturing firms in Tanzania. Thus, the supply of locally processed tomato sauce (an important component of various food cuisine and food menus in Tanzania) has been increasing (Hawassi, 2006).

Given the considerable importance of consumption of locally processed tomato sauce, it is essential to investigate if tomato processing firms in Tanzania adhere to food safety and quality control practices (FSQCPs). The joint public initiative for strengthening food safety and quality control system by the regulatory authorities, for example, Tanzania Bureau of Standards (TBS) and the then Tanzania Food and Drugs Authority (TFDA), emphasizes that food processing firms adopt FSQCPs as an essential requirement for ensuring public health in Tanzania. Thus, the current study confines its scope to food hazard analysis in the locally processed tomato sauce by the tomato processing firms in Iringa and Dar es Salaam regions.

1.2 Problem Statement and Justification

In Tanzania, food regulatory authorities (FRAs) have directed the food processing firms to adopt FSQCPs with a view of ensuring food safety (TFDA, 2012). However, the empirical evidence on hazards of locally processed food, particularly tomato sauce, is severely insufficient in the literature (Kahindi, 2016). Specifically, little is known regarding the extent to which FSQCPs have been adopted by tomato processing firms in Tanzania. Thus, such insufficient evidence has potentially contributed to a failure of FRAs and policymakers to gauge the implications of adoption of FSQCPs on food safety and public health. For example, farmers have been using pesticides, of which organophosphates and synthetic pyrethroids are predominant (Vemuri *et al.*, 2014). Unfortunately, farmers are not systematically implementing good agricultural practices (GAP). While there is a potential that certain pesticides residues may remain in the final products of tomatoes (Gamacorta *et al*., 2005; Essumang *et al*., 2008), in Tanzania there is a scarcity of empirical evidence on this question, which hinders FRAs to draw evidence-based interventions. Despite the insufficiency of evidence, average consumption of processed tomato products (e.g., tomato sauce, ketchup, paste, and dried tomatoes), based on the official import data, stood at 1,552.64 MT (in 2014) and increased up to 2,071.93 MT (in 2019), implying a growth of 33.45% during the period under review (TRA, 2020).

According to Corlett (1998), most of the studies on food safety tend to emphasize on food regulations and measures required to develop and enforce the conformity to the food safety regulations, education, and technical sophistication by food processing firms and retailers. Few studies have been carried out to address the preventive measures of food hazards. In a particular case of Tanzania, previous researchers have studied the subject of food hazards in food sub-sectors other than tomatoes. Kussaga *et al.* (2014a; 2014b) focused on analysing food safety management systems in the dairy and fish processing and Kamala *et al*. (2016; 2018) studied fumonisins and aflatoxins in fresh and stored maize. Also, Kamala *et al.* (2015) analyzed the co-occurrence of multiple mycotoxin in maize from three agroecological zones of Tanzania.

It follows, therefore, that the current study is an attempt to narrow down the exisiting gap in the empirical literature by exploring the current situation about types of hazards as well the sources and actions taken to control them in the tomato sauce processing lines. It establishes the extent to which tomato processing firms adopt the recommended practices towards food safety.

1.3 Significance of the Study

As pointed out in the sections that follow, it is worthy to appreciate the firm-level production management practices leading to the safety of tomato sauces because in so doing it gives evidence that is important to public health and product competitiveness. Therefore, the significance of this dissertation is twofold. First, the findings in this dissertation provide empirical evidence regarding the firm-level adoption of food safety and quality control practices (FSQCPs) along the tomato sauce processing lines for ensuring food safety. Such evidence forms one of the fundamental tools to educate consumers, food regulatory authorities (FRAs), small and medium-sized food processors, and retailers concerning the implementation of practices that guarantee food safety.

Second, since this study standout as a preliminary attempt, the findings provide a starting point for further comprehensive studies to drive the adoption of HACCP and or food safety plan (FSP) to other food processing value and supply chains in Tanzania. This is particulary important for Tanzania's agroprcessing sector during the current era of government flagshing policy of promoting an inclusive industrialization and, by buidling on Sonobe (2019), encourages campanies to continously underake industrial upgrading for the country ambition to realize a middle income status by 2025 as articulated in the Tanzania Development Vision 2025 (URT, 2000).

1.4 Research Objectives

The main objective of this study was to analyze the food hazards in the locally processed tomato sauces in processing companies in Iringa and Dar es Salaam regions. The specific objectives of the study were:-

(i) To identify sources of the hazards and actions taken by tomato processing firms to correct them;

(ii) To assess the adoption of food safety and quality control practices (FSQCPs) in the tomato sauce processing firms; and

(iii) To analyse the microbial pathogens and the levels of pesticide residues, in the processed tomato sauce.

CHAPTER TWO

2. LITERATURE REVIEW

To inform this study, the review of literature is divided into four major parts. While the first part defines key terms used throughout the dissertation, the second part deals with food hazards commonly found in the raw as well as processed tomatoes. Such hazards, which are rampant in case the food safety processes are not adhered to; include microbial, physical, and chemical hazards. The third part captures a review on the food safety management practises, including the application of HACCP and food safety plan (FSP), in food processing firms. Lastly, the fourth part summarises the literature review by revealing the literature gaps (of which this study attempts to narrow down).

2.1 Definition of Key Terms

Like other scholarly works, this dissertation employs a vast number of technical terminologies. On the one hand, such terminologies may be easily understood by the subject matter specialists. On the other hand, however, the same may not be straightforwardly comprehended by other audiences. Thus, to support a harmonized understanding among interested readers of this dissertation from various backgrounds, this section introduces and defines such key terminologies used in this study.

Hazard Analysis is the process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan (Pierson, 2012). It is the first principle in HACCP development. Before a HACCP plan is developed, there are preliminary steps that have to be carried out. It is very important to honestly and logically conduct the preliminary steps in the HACCP development. If the preliminary steps are honestly and logically carried out before the first principle, it helps to minimize any possible hazards that may occur during food processing (FAO and WHO, 2010).

Hazard Analysis and Critical Control Point System (**HACCP**) as defined by the Codex Alimentarius Commission (2010), HACCP is a management system which applies good practice that identifies, evaluates and controls hazards which are significant for food safety. The HACCP system consists of seven basic principles that meet the stated goal. These principles include conducting a hazard analysis, identification of critical control points (CCPs), establishing critical limit(s), establishing a system to monitor control of the CCP, developing the corrective action to be taken when monitoring indicates that a particular CCP is not under control, establishing procedures for verification to confirm that the HACPP is working effectively, and documentation concerning all procedures and records appropriate to these principles and their application. According to NACMCF (1998), in the food manufacturing industry, HACCP is a worldwide-recognised systematic and preventive approach that tackles biological, chemical, and physical hazards through anticipation and prevention, rather than by end-product inspection and testing.

Critical Control Point (**CCP**) is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Pierson and Corlett, 1992).

Food Safety Plan (**FSP**), according to NACMCF (1998), is a plan based on the concepts of Hazard Analysis and Critical Control Point (HACCP). Generally, FSP consists of the primary documents in a preventive control food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne diseases or injury. It contains a collection of written documents that describes activities that ensure the safety of food during manufacturing, processing, packing, and holding (Pierson, 2012).

Food Safety Hazard (**FSH**) refers to any agent with the potential to cause adverse health consequences to consumers (Batt, 2016). It occurs when food is exposed to hazardous agents which result in contamination of that food. Food hazards may be biological, chemical, physical, allergenic, nutritional and/or biotechnology-related.

Food Safety and Quality Control Practices (**FSQCPs**) includes several quality management concepts, comprising the monitoring of undesired components and the authentication of the food product itself (FAO and WHO, 2010). Such quality controls practices may comprise, but not limited to, Good Agricultural Practices (GAP), Good Manufacturing Practices (GMPs), Good Hygienic Practices (GHPs), Hazard Analysis and Critical Control Point (HACCP) Systems.

Good Agricultural Practices (**GAPs**) refers to the best practices used for producing agricultural products to ensure the quality and safety of the final product (FAO and WHO, 2010). In general, the products are crops, commodities and foods of animal origin. Hence, GAPs are applied on the farm and where animals are reared for food, GAPs address a range of agricultural practices with the view to prevent food safety hazards being introduced from the environment or through the application of modern farming methods.

Therefore, it includes use of fertilizers, pesticides, and veterinary drugs, possible contamination from soil, and water.

Good Manufacturing Practices (**GMP**) is a bundle of management practices for ensuring that products are consistently produced and controlled according to quality standards (IFST, 2012). GMP is designed to minimize the risks involved in production process that cannot be eliminated through testing the final product. It covers all aspects of production from the starting materials, premises, and equipment to the training and personal hygiene of staff.

Good Hygienic Practices (**GHP**) is the implementation of the essential principles of food hygiene applicable throughout the food chain (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption (ITC, 2017). It is worth to take note of the General Principles of Food Hygiene apply to both GAP and GMP through the implementation of GHP. Actually, GHP recommends a HACCP-based approach to reduce risks.

Foodborne Diseases (**FBD**), an outcome of poor hygiene practices, is defined as any disease caused by the spoilage or contaminated food, pathogenic bacteria, viruses, or parasites that contaminate food (Ababio *et al*., 2016). In many instances, FBD arises from improper handling, preparation, and storage of food. As argued by Humphrey *et al*, (2007), therefore, good hygienic practices before, during, and after food preparation can reduce the probability of contracting FBD.

Food Contaminants (**FCs**) are any harmful substances unintentionally added to food (FAO and WHO, 2010). Food can be contaminated by toxic metals, chemicals (e.g., pesticides and veterinary drug residues), radionuclides and mycotoxins from the natural sources, environmental pollution, or formed during food processing.

2.2 Food Hazards Related to Tomatoes

Tomato is the next most important vegetable crop after potato in the world (Wakil *et al.*, 2018). In the case of Tanzania, about 423,323 MT of tomatoes are produced annually (FAO, 2015). Despite being produced in large numbers, tomato is a seasonal and perishable vegetable. It is, therefore, necessary to process tomato so as to increase its shelf life and to make it available during off seasons. Tomatoes can be processed into various tomato products such as sauce, paste, ketchup, chutney, puree, jam, juice or squash, and base of other sauces (e.g., chilli and garlic). Also, it provides a medium for baked and canned products such as beans, maize, and carrots (SIDO and MIT, 2009).

Fresh produce has been linked with pathogens, public health and trade implications (FAO, 2008). There are several factors that may result to the microbial contamination of fresh produce at the lowest level of production. Microbial contamination may, in the long-run, pause a risk of foodborne disease. Contamination factors may include hygiene of the environment where the food is prepared, water for primary production and packaging, food handlers and the sanitary facilities in the production area.

Also, chemical contamination has been linked to contamination of tomatoes. A number of pesticides are used in the production of fruits and vegetables because fruits and vegetables are easily attacked by diseases and pests. According to Bempah *et al*. (2012), these pesticides then get their way into organisms through food. It is equally important to note that the amount of pesticide usage has been recently reported to be increasing annually in the production of horticultural produces in Tanzania. Although there is an increase in use of pesticides and other types of agrochemicals, most of the smallholder farmers, who by and large dominate farm production in the horticultural sector of Tanzania, are not aware on how to properly handle and use those pesticides (Ngowi *et al*., 2007).

2.2.1 Chemical Hazards

A chemical hazard is any substance that can cause a health problem when ingested or inhaled. They include toxins, dangerous chemicals, and residue of excess chemicals used in agriculture and processing food products. With respect to different food industries, the food may be contaminated at any discrete point in the production line through, for example, air, water, or any other natural source. There are different types of chemical hazards, and this includes naturally occurring food chemicals, intentionally added food chemicals, unintentionally added food chemicals and food allergens. The chemicals may enter the food through the ingredients or raw materials used or somewhere in the processing unit where product is treated with various chemicals (Nerín *et al*., 2016).

Chemical hazard may also be due to metabolites produced by microorganisms (e.g., certain moulds of *Aspergillus sp* that produce aflatoxins). According to Lawley *et al.* (2012) either immediate or long-term exposure to chemicals in food can cause illness or injury. In tomato industry, it is likely that the residues of chemical fertilizer and pesticide, especially during farm production of tomato, may be among the common chemical hazard in tomato products (Essumang *et al*., 2008; Kwon *et al*., 2015).

2.2.2 Microbial Hazards

Microbial food contamination may be caused by a number of organisms such as virus, bacteria, fungi and moulds (Majeed, 2017). Microbial contamination of food may occur during growth and harvesting of raw materials, processing into finished products and transportation of both raw materials and finished products. Sometimes contamination may also occur right before consumption (Nerín *et al*., 2016). In most cases, contamination may result from the contact with preparation surfaces, environment (air and water), and food handlers. If the contamination is not taken care off in the appropriate time, then the microorganisms can multiply and pose a health risk to the consumers. In food processing, proper food handling is very important to ensure that microbial contamination does not occur and if it occurs then it should not be allowed to multiply and pose any health risks (Vemuri *et al*., 2014).

According to Omolaran *et al*. (2016), the most common microbial contamination in tomatoes is caused by bacteria (*Staphylococcus aureus* and *Bacillus spp*) and fungi (*Aspergillus flavus* and *Rhizopus stolonifer*). These microorganisms cause the tomato to rot and discolor. The number and type of microorganisms in the final processed product depends on various factors. These include the initial number of the present microorganism, the temperature of the final product, distribution time and the atmosphere in which the final product is kept (Zagory, 1999).

2.2.3 Physical Hazards

Physical hazard includes the presence of foreign objects in food that can cause harm. Examples of such foreign objects include glass, metal fragments, and hair (Lawley *et al*., 2012). When a consumer mistakenly ingests the foreign material or object, it is likely to cause choking, injury or other adverse health effects. Indeed, among the three categories of food hazards, physical hazards are the most commonly reported consumer complaints. In part, this is because the injury occurs immediately or soon after eating, and the source of the hazard is often easy to identify.

2.3 Food Safety and Quality Control Practices

Failure to adopt food safety and quality control practices (FSQCPs), especially at food processing firm level, is one of the major causes of food hazards (Lawley *et al*., 2012). As pointed out earlier, there are several approaches of FSQCPs (e.g., HACCP, GMP, GAP, and GHP). While HACCP is a preventive approach, GAP, GMP, and GHP are prerequisites for smooth operation of HACCP (Wallace and Williams, 2001). To define the kind of hazard in a particular food industry is important. Depending on the type of food being processed, contamination can take place through the air, water for production, food handlers and other natural sources. With regard to chemical hazards, they can get into the food anywhere along the production line (Rather *et al*., 2017)

When FSQCPs are put into action and when they are well implemented, it guarantees a trusted market for the food manufacture. Also, it builds confidence of the clients and employees on the product quality. Indeed, FSQCPs ensure efficiency because only the best practice of the process will be adopted by the food manufactures. In turn, this potentially guarantees the best quality product. It is, therefore, important to define what kind of hazard is possible to occur in a particular food industry.

2.4 Emerging Gaps in the Literature

From the literature reviewed, so far, it is evident that there are knowledge gaps. First, the vast majority of the empirical studies available were conducted in the developed countries. Yet, another knowledge gap is related to food hazard analysis on product-specific, particularly in the context of a developing country. In developing countries, mostly those countries in the sub-Saharan Africa (SSA), including Tanzania, the small and medium size manufacturing enterprises dominate (Sonobe and Otsuka, 2014; NBS and MITI, 2016;

Higuchi *et al*., 2020; Hosono, *et al*, 2020). However, such firms have limited hands-on production management skills to guarantee high product quality and productivity as reported by Bloom and van Reenen (2007), Bloom *et al*. (2013), and Bender *et al*. (2018). Therefore, this dissertation attempts to analyze the food hazards in tomato sauce. Using a product-specific approach, the analysis is confined to the locally processed tomato sauces among the selected small and medium scale tomato processing firms located in Iringa and Dar es Salaam. To achieve the aforesaid analysis, the study undertakes three key issues. First, it identifies the sources of the hazards and actions taken by tomato processing firms to correct them. Second, it assesses the adoption of food safety and quality control practices (FSQCPs) in the tomato sauce processing firms. Third, it seeks to evaluate the microbial load and the levels of pesticide residues, in the processed tomato sauce.

CHAPTER THREE

3. MATERIALS AND METHODS

This chapter discusses the methodology adopted in carrying out this study. Specifically, it describes the study area, materials used and methods applied to capture data, and the analytical approach to generate information to inform the study.

3.1 Study Area

This study was carried out in Iringa (two firms in the municipal and one firm in Masukazi village, Kilolo District) and one firm in Dar es Salaam. The two regions are among the twenty-six (26) administrative regions of Tanzania Mainland. According to the Industrial Census of 2013, in the municipal councils of both regions, there are small-sized tomato processing firms (NBS and MITI, 2016). While on the one hand Iringa region (7º46'S 35º42'E) is predominantly a major producer of tomatoes in Tanzania, on the other hand, Dar es Salaam (6º48'S 39º17'E) is a major market destination of both tomato and tomato products (BCS and CSDI, 2009; WB, 2018). Also, in both regions, processed tomato products (of different varieties, such as tomato sauce, paste, ketchup, and dried tomatoes) are available in the food stores, hotels, restaurants, and supermarkets.

3.2 Materials

The materials included samples of tomato sauce. Samples were purchased from the processing firms in Iringa and Dar es Salaam. Analytical food reagents and chemicals were obtained in the accredited food laboratories of Tanzania Industrial Research and Development Organization (TIRDO) in Dar es Salaam and Tanzania Pesticide Research Institute (TPRI) in Arusha.

3.3 Methods

3.3.1 Research design

In this study, a cross sectional research design was used. In part this was attributed to the limited resources (including time). To achieve that, three steps here were followed.

First, the sample of frontline workers, who work along the tomato processing lines, were randomly selected to get requisite information related to production flow chart/diagram the sources of food hazards, action taken, and the extent of the adoption of FSQCPs. Hence, a cross-sectional survey design was implemented among the sample workers of the sample tomato processing companies. A structured questionnaire, which is attached as Appendix 1, was used to collect such information from the workers and checklist to collect additional information from the key informants (mainly line managers and supervisors in each tomato processing firm covered by the study). It is important to note that the level of willingness to share such information is in line with common practices that processors are not readily willing to share some of their information in fear of leaking it out to other companies. In this study, whenever such a circumstance emerged, the researcher worked jointly with the production and quality control team of the company under study with a view of constructing a process flow diagram.

Second, the samples of tomato sauce of different batches were randomly selected from each processing firms in Iringa and Dar es Salaam. Ten (10) samples were collected from each firm from different batches. Thus, a total of 40 samples were analyzed to evaluate the microbial, chemical, and physical contaminants in the samples of tomato sauce.

Third, on site observation at each stage of production following the production flow chart was conducted to verify the possible hazards related to tomato processing. The adoptions of FSQCPs by the firms to minimize the contamination of the final product were assessed using a questionnaire and observation during the site visit.

3.3.2 Analysis of food hazards in the sample tomato processing companies

As was previously stated in Section 1.4, one of the specific objectives of this study was to identify the sources of food hazards and actions taken by tomato processing firms to correct them. Food hazard analysis should be carried out to ensure the production of safe products in any food industry and that, according to FDA (2018), there are three key issues that should be considered prior to conducting food hazard analysis. First is to assemble a food safety team. In this study, I did the work of the food safety team. The second one is to describe the key features of the final product (in this case "tomato sauce") as per the established standard, namely, Tanzania Standard (TZS). Third is clarification of the intended use of the product and its mode of distribution (which was seen to be done in vans with cold rooms). To identify the hazards, a table was constructed to show the ingredients /processing followed by identifying hazards introduced at each step and its control, to identify the potential food-safety hazard and their significance, these steps are then justified. After these steps, steps that determine critical preventive measures to avoid significant hazards are determined and lastly, a step is devised to control the hazard.

As per the requirement of the first principle of HACCP, after considering the three items mentioned above (i.e., assembling of the HACCP team, product description, and description of the intended use of the product), HACCP team has to establish the process flow diagrams (that is, a step-by-step visual guide to different processes) for each product processing. The process flow diagrams were established through two approaches. That is, while one company generously provided its process flow diagram voluntarily, for the remaining three companies, the process flow diagrams were jointly constructed (and confirmed) through on-site verification.

3.3.3 Sampling technique and sample size

Simple random sampling was used to get workers to be considered for structured interviews. Such workers are those who work for a tomato processing firm in any point along the tomato processing lines. As recommended by Kothari and Gaurav (2014), the sample size of frontline workers for this study was estimated using equation (3.1).

$$n = \frac{Z^2 pq}{e^2} = \frac{Z^2 p(1 - p)}{e^2} \tag{3.1}$$

whereby n is the sample size, p stands for sample proportion (which is assumed to be 0.05), e captures the acceptable error or the precision (set at 0.05), and Z is the standard variate at a given confidence level (i.e., 95% confidence level = 1.96). It follows, therefore, that the estimated sample size is 73 frontline workers as numerically computed in equation (3.2) below.

$$n = \frac{1.96^2 \text{ x } 0.05(1 - 0.05)}{0.05^2} = 72.99 \approx 73 \tag{3.2}$$

The study is designed to cover four tomato processing companies. Such companies are relatively similar in size. According to NBS and MITI (2016), each of the sample firm has about 35 employees. Thus, the anticipated sample size of 73 frontline workers was equally distributed to each company. That is, in each company, at least 18 workers along the tomato processing line were randomly selected for interview. There are at least 9 stages that defines tomato sauce processing line (Gould, 1992). Hence, at least 2 workers were randomly picked from each stage to make a total of at least 18 workers for a sample company.

3.4 Analysis of Food Hazards

3.4.1 Determination of microbial contaminants

Microbiological analysis involved enumeration of total viable counts (TVC), total coliforms, *Escherichia coli* and *Staphylococcus aureus*. Analytical sample were prepared according to Andrew and Hammack (2018). A 25 g of tomato sauce sample was taken and blended with 225ml of buffered peptone water for analysis of total viable counts, total coliforms, *E. coli* and *S aureus*. Appropriate enrichment and selective media were used for each indicator microorganism. Enumeration of total viable counts (TVC), total coliforms, *E. coli*, and *S. aureus* was performed according to ISO 4831:2006(E) (ISO, 2006), ISO 7251:2005(E) (ISO, 2005), and ISO 6888–3(E): 2003 (ISO, 2003) methods, respectively.

3.4.2 Determination of chemical contaminants

An overall presence of the pesticide residue was determined by the Multi–residue Analysis of pesticides using Gas Chromatography Mass Spectrometry (GC-MS). The samples were homogenized by homogenizer then 15 g of each sample was transferred to 50 ml centrifuge tube. Internal Standards and 10 ml acetonitrile was then added and shaken vigorously for a minute. Then it was centrifuged at more than 3000 rcf for 5 minutes.

A salt portion was then added to all the samples. Magnesium Sulphate Anhydrous 4 g, Sodium acetate 1.5 g and Sodium chloride 1 g was added to all the samples and shaken vigorously and then centrifuged for 5 minutes for separation. Cleaning of all the samples was done by adding 2 ml supernant in 15 ml centrifuge tube and $MgSO_4$ 300 mg and silica gel 150mg.Then samples were the put in the GC-MS machine and left for 24 hours.

3.4.3 Determination of physical contaminants

Samples of the final products were poured on trays to determine the presences of physical contaminants. Magnets were used to detect the presence of any unwanted metals. Sieving of the tomato was done using a 1mm sieve to check for the presences of things like grass, soil particles, hair, tomato peals, and the likes.

3.4.4 Questionnaire design and administration

A structured questionnaire (Appendix 1 attached) with close-ended questions was adopted to collect qualitative data from tomato processors. The questionnaire was inscribed in English and, during the interviews, it was administered in Swahili, a Tanzanian national language. It constituted two sections; section one was designed to capture socio-demographic information of the respondent (e.g., age, sex, level of education number and years in the food processing industry) and section two captured GHP and GMP practices.

CHAPTER FOUR

4. RESULTS AND DISCUSSION

This chapter presents and discusses the results based on the specific objectives which guided this study. The chapter begins by clarifying the basic characteristics of the sample companies. Thereafter, the discussion of the major analytical findings, that is, those related to analysis of food hazards, quality control practices, and microbial pathogens and pesticide residues, follows.

4.1 Basic Characteristics of the Tomato Processing Firms

The basic information characterizing the four tomato processing companies is shown in Table 1. As Table 1 shows, the three sample companies are located in Iringa municipal, one is Dar es Salaam. According to the interviewees, the dominance of Iringa in terms of larger number of tomato processing firms than Dar es Salaam may be potentially ascribed to the fact that Iringa region accounts for about 72% of the total national production of tomato (BCS and CSDI, 2009; WB, 2018). Thus, while holding other factors constant, due to proximity to raw tomatoes (the major raw material), entrepreneurs find it convenient and cost effective to establish processing facilities in Iringa.

Also, Table 1 reports that all the processing companies (100%) were registered with a food regulatory authority either TBS or by the then TFDA or both as a requirement that all food processing firms register their premises before production of any food commodity (TFDA, 2012). On average, all the sample companies had more than ten employees but less than fifty, implying that they are all small in size (MIT, 2003). Level of education for the personnel responsible for quality assurance showed that 50% of them had a degree related to food quality or food processing. The rest had either a diploma in food science or ordinary secondary education.

Table 1: Basic Information of the Respondents

Location	Category	Frequency	Percentage
	Iringa	3	75
	Dar	1	25
	Total	**4**	**100**
Registration	Yes	4	100
	No	0	0
	Total	**4**	**100**
Number of Employees	Less than 5	0	0
	5-10	0	0
	11-50	4	100
	Total	**4**	**100**
Level of Education of the supervisors	Ordinary Secondary	1	25
	Advanced Secondary	0	0
	Certificate	0	0
	Dip	1	25
	Degree	3	50
	Masters	0	0
	Total	**5**	**100**
Experience	Less than 5	1	25
	5-10	2	50
	More than 10	1	25
	Total	**4**	**100**

Source: Field Survey, 2018

Table 1 also shows that about 50% of the personnel responsible for quality assurance had experience between 5-10 years in the food processing. The rest had either less than 5 years (25%) or more than 10 years (25%) of experience in food processing industry. These findings may suggest that the human resource of the sample companies have accumulated necessary hands-on skills which, as pointed out by Bloom *et al*. (2013) and Sonobe and Otsuka (2014), are necessary for management of industrial production.

4.2 Analysis of Food Hazards

4.2.1 Specification of the final products

According to TBS (2018), TZS 160: 2018-EAS 66-2:2017 (3rd Edition) published by East African Community (EAC), tomato sauce is described as the one that comply with the compositional requirements indicated in Table 2 when tested in accordance with the methods prescribed there. Even though, the scope of this study was not designed to confirm the compositional requirements describing tomato sauce, yet seen information based on the label for each sample company revealed compliance to the compositional requirements of tomato sauce.

Table 2: Description of Tomato Sauce

S/N	Characteristic	Requirement	Test Method
(i)	Total soluble solids content, percent by mass	18–25	AOAC 920.151
(ii)	Sodium chloride, percent by mass, max.	6	AOAC 971.27
(iii)	pH	Not higher than 4.5	ISO 1842
(iv)	Specific gravity at 20 ºC	1.074 13–1.105 64	EAS 66-2:2017

Source: Adapted from TBS (2018)

However, during the fieldwork, it was noted that, although tomato was the major ingredient for all the sample firms, the said tomato processing firms showed slight difference in the ingredients used (within the acceptable threshold by TBS) for tomato sauce processing. The specific examples of such ingredients are preservatives (i.e., *Acetic acid* and *Sodium benzoate*) and flavouring agents (i.e., *Xantam gum*). It was explained by the interviewees that such difference was partly attributed to the target market of each company.

4.2.2 Intended use

As to the intended use of the final product, it was clarified by the firm owners that tomato sauce was (and continues to be) intended to be used mainly as a condiment and in some cases as a food spice in other food cuisines. The final product is to be used by all the age group of various consumers as it has no restrictions on the use by age. In terms of product distribution, all processing firms used trucks for the transportation. However, during the fieldwork such vehicles were seen undertaking product distribution without having inbuilt cold facilities. As such, this is likely to be one of the shortcomings of the distribution mode because, in order to maintain standard temperature, tomato sauce requires to be stored in a cool dry place of less than 25^0C all the time.

4.3 Hazard Analysis of Company A

Company A is located in Iringa region, and the company has approximately 40 workers. The company has a total of 2,000 m^2 area in coverage and this allows the company to have well-constructed and spaced structures to ensure a smooth production process. The company has water and waste treatment plants with a specific technical team to attend to the water treatment. There are special areas for the receiving, sorting, and storing of the all raw materials. The product movement is unidirectional and most of the processing is done in closed systems. This means that the interaction between the personal and the product is very much minimised.

4.3.1 Process Flow Chart

Figure 1 represents a process flow diagram for company A. The three noticeable features in Figure 1 in relation to processing of tomato sauce are the adoption of a comprehensive process of tomato sauce production, good manufacturing practices (GMP), and HACCP certified.

Another reason provided by the quality control manager of this firm is market force. The company produces tomato sauce for market with high purchasing power and for export to Kenya and Rwanda, Southern Africa, Malawi, Zimbabwe, and Mozambique and to other European countries. This is explanation is supported by export data requested from Tanzania Revenue Authority (TRA) indicating that, the company has been exporting tomato sauce (and other related products) either by company A or a number her intermediary traders to those countries (TRA, 2020).

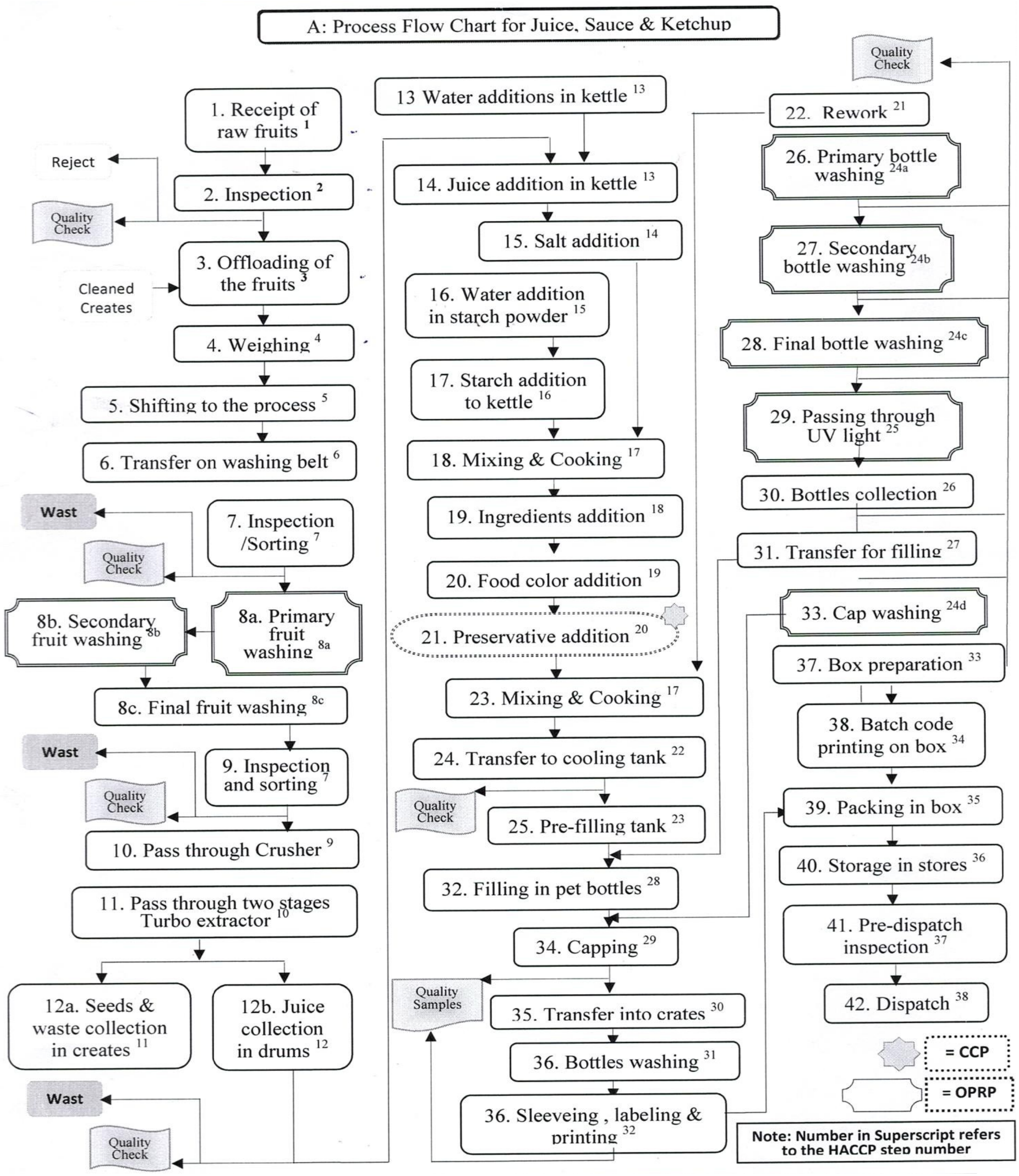

Figure 1: Process Flow Chart Diagram of Company A

Source: Company A, 17/01/2020

4.3.2 Description of Process Flow Chart

During the field visit, it was revealed that quality control personnel in the company were aware of the process flow of tomato sauce process and they ensured there was no contamination. This was evidenced by the said personnel wearing protective gears and unidirectional movement of both personnel and tomato sauce being processed. The equipment that was used during the production process comprised of stainless steel. In case of cold ingredients and spices food grade plastic was used for weighing. Portable water that was treated from the water treatment area was used in both cleaning and the production process. Quality checks were done along the production process by checking the production temperature, bricks of the product was checked as well as the pH, this was done to ensure that there was contamination along the production line and if there was any contamination then it was to be taken care of before the final product.

The storage of the raw materials as well as the finished products was in clean rooms with temperatures' below 25ºC. This is to ensure that there is no growth and hence spoilage of both the raw materials and finished products. During processing, there was very minimal handling by the workers as this was done in machines. The workers only handled the raw materials before they were feed into the processing machine. The processing machines were washed with portable water, soap and disinfectants. There was a thorough rinsing and pH of the rinsing water checked to ensure that there was no risk of contamination of the product with either soap or disinfectant. After production, the final product was packed in food grade containers which were either plastic or glass.

4.3.3 Hazard Analysis Table for Company A

After working on the process flow diagram of company A, Hazard Analysis Table (HAT) of the same company is presented to show whether the control point is critical or not. Therefore, Table 3 below shows production, potential hazard identification and determination of the significance of the hazard, decision justification, preventive measures, and its control with respect of company A.

Table 3: Hazard Analysis Table for Company A

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) Ingredients/Processing step	**(2) Identify potential hazards introduced, Controlled or enhanced at this step**	**(3) Are any potential food-safety hazards significant (YES/NO)**	**(4) Justify the decision for column 3**	**(5) What preventive critical measures can be applied to prevent the significant hazard**	**(6) Is this step a control point? (YES/NO).**
Raw material receipt (tomato)	P. Presence of foreign matter from farm(grass, stones, pieces of broken wood from the boxes used to carry the raw tomatoes,)	No	There is sorting and sieving process down stream	Inspection of the raw materials	No No
	C. Agrochemical residue from farm, grease may be present from the trucks used for carrying the raw tomatoes	No	Pealing and washing reduces the levels to acceptable levels	GMP, GAP, and GHP	No
	B. *Staphylococcus aureus, E. coli, Salmonella typhi* from	No	There is cooking		

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Other Ingredients receipt	the farmers and factory personnel		and pasteurization later in processing		
Inspection	At this stage the fruits are check to see that the above-mentioned hazards are not present.	No	If any of the hazards are noted then the whole consignment is rejected at receipt	Thorough inspection of the consignment Receiving of consignment from reliable suppliers who have been entrusted and issued with CoC Proper checking of CoC from suppliers	No

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Offloading of the fruits	B. The tomatoes are offloaded manually by the workers down for weighing and later emptied into tanks, this may cause bruises to the tomatoes which may initiate the growth of unwanted microbes. P. pieces of broken wood from the creates used to carry the tomatoes	No No	There is sorting, washing and cooking along the production line	Proper offloading of the fruits from the transport trucks The workers handling the tomatoes at this point are medically tested every after three months, they are exempted from work when they fall sick and they are always wearing protective clothes during food handling.	No

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Weighing Transfer to the washing belt. Inspection / sorting	The tomatoes are emptied into big buckets for weighing. The buckets are clean as they are washed every after a production process. No potential hazards at this stage. This is done manually. The workers are always wearing their protective gears. The not well ripen fruits are separated from	No -	Clean crackles buckets do not pose any risk of contamination to the tomatoes. -	The weighing equipment should be kept clean and in good condition always. -	No - Yes

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**		
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**		
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**		
Date:					
(1) Ingredients/Processing step	**(2) Identify potential hazards introduced, Controlled or enhanced at this step**	**(3) Are any potential food-safety hazards significant (YES/NO)**	**(4) Justify the decision for column 3**	**(5) What preventive critical measures can be applied to prevent the significant hazard**	**(6) Is this step a control point? (YES/NO).**
Primary and Secondary fruit washing	the ripen fruits. Rotten tomatoes are also removed. P. Grasses and stones from the farm C. Non B. Staphylococcus, yeast and moulds that may be present in bruised and over ripen tomatoes At this stage, fruits are washed with treated warm water.	No No Yes No	There is sieving down the proses line There is cooking proses	Sieving Monitoring cooking time and temperature.	No No

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Final fruit washing	P. None C. Excess chlorine from the treated water B. None				
Inspection and sorting	P. None C. None B. None P. Stones and grasses	Yes	There will be no more sorting and cleaning down the process line.		YES

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Crushing	C. Chemicals that may be introduced through washing water B. Bacteria, moulds and yeast from rotten and bruised fruits At this stage, the cleaned fruits are passed through a crusher. The crusher is in good condition. It is made of stainless steel therefore does not have rust and it is also clean. P. None	No	The crusher is in good condition i.e it is not rusted and it is well cleaned. There are no grease spills that may cause contamination to the food.	Physical hazards are inspected physically and by magnets, cleaning water pH is checked to prevent chemical contamination, over ripen fruits are removed The crusher should always be in good working condition	No

Company Name: **Firm A**		**Product Description:**		**Tomato sauce**	
Firm Address: **IRINGA**		**Method of storage and distribution:**		**Stored at room Temperature**	
Signature:		**Intended Use and Consumers:**		**Used as cooking spice and condiment**	
Date:					
(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Passing through two stages turbo extractor.	C. None B. None P. None	No	The extractor is in good condition. The sieves are intact which does not allow for seeds and other wastes to pass through.		No
Juice collection in drums and seeds and waste are collected in creates.	C. None B. None P. Foreign objects that might be inside the drums	No	The drums are inspected before use and they are of food grade material	The turbo extractors should be always in good condition i.e., the sieves should be intact and clean all the time.	No

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) Ingredients/Processing step	**(2) Identify potential hazards introduced, Controlled or enhanced at this step**	**(3) Are any potential food-safety hazards significant (YES/NO)**	**(4) Justify the decision for column 3**	**(5) What preventive critical measures can be applied to prevent the significant hazard**	**(6) Is this step a control point? (YES/NO).**
	C. If the drums are not food grade it might lead to reaction with the tomato juice B. Not well cleaned drums might introduce microbes in the fruit juice.			The drums are stored in an aseptic manner, inspected before use and of food grade material	
Addition of the fruit juice and water in kettle	P. Introduction of foreign matter from water C. Water may contain chemicals (chlorine) B. *Staphylococcus aureus*, *E. coli* and coli forms from processing	No	Use of treated water	Water is checked for pH and microbiology before use and the kettle is cleaned and inspected before use.	Yes

Company Name: **Firm A** **Firm Address:** **IRINGA** **Signature:** **Date:**		**Product Description:** **Method of storage and distribution:** **Intended Use and Consumers:**		**Tomato sauce** **Stored at room Temperature** **Used as cooking spice and condiment**	
(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
	water				
Addition of salt and starch in kettle	P. Foreign particles in salt and the starch powder. C. None B. None	No	salt and starch used are ensured to be of good quality and from approved suppliers	The starch and salt are obtained from approved suppliers, they are stored in cool and dry place to avoid contamination and growth of microorganisms and they are checked before use.	No
Mixing and cooking	P. None	No	The products being mixed are ensured that they are of		No

Company Name: **Firm A** **Product Description:** **Tomato sauce**

Firm Address: **IRINGA** **Method of storage and distribution:** **Stored at room Temperature**

Signature: **Intended Use and Consumers:** **Used as cooking spice and condiment**

Date:

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
	C. None B. None		good quality; the mixer is in good condition ie no rust and clean before use.		
Ingredients, food colour and preservative addition	P. None C. Unpermitted food colour and preservatives, expired food colour and preservatives B. Bacteria, moulds and	Yes	The use of unpermitted food colour and preservatives and expired products may lead to food contamination. There is great possibility of the ingredients to	The company has ensured that they use permitted food colour and preservatives. The ingredients are preserved in cool dry places and inspected before use to prevent microbial contamination.	YES

Company Name: Firm A **Firm Address:** IRINGA **Signature:** **Date:**		**Product Description:** Tomato sauce **Method of storage and distribution:** Stored at room Temperature **Intended Use and Consumers:** Used as cooking spice and condiment			
(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
	yeast		contain microorganisms if not well preserved.		
Mixing and cooking	P. None C. None B. None	No	All the ingredients and equipment have been thoroughly checked before mixing.	Proper monitoring of the cooking time and temperature done by the company is essential.	No.
Transfer to cooling tank and then to pre-filling tank.	P. None C. None	Yes	The cooling and pre-heating tanks are to be checked for cleanliness before being used.	The Tanks are cleaned in place ensuring that they are thoroughly rinsed. The final rinsing water is subjected to laboratory test to ensure absence of	No

Company Name: **Firm A** **Product Description:** **Tomato sauce**

Firm Address: **IRINGA** **Method of storage and distribution:** **Stored at room Temperature**

Signature: **Intended Use and Consumers:** **Used as cooking spice and condiment**

Date:

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Filling in pet bottles	B. None P. Dust in the bottles C. Chemicals from bottle washing detergent B. microbes from dust in the bottles.	No	All the hazards are taken care off by thorough washing and inspection of the bottles before use All the hazards are taken care off by thorough washing	chemicals and microbes. There is primary, secondary and final washing of the bottles. The bottles are then passed through UV light for disinfection There is cap washing where portable water is used and the water is tested in the laboratory to check for its safety.	No

Company Name: Firm A	Product Description: Tomato sauce				
Firm Address: IRINGA	Method of storage and distribution: Stored at room Temperature				
Signature:	Intended Use and Consumers: Used as cooking spice and condiment				
Date:					
(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Capping	P. Dust in the bottle caps C. Excess chemicals from the water used to wash the caps. B. Microbes from dust in the bottles.	No	and inspection of the bottle cappings before use The tomato sauce is already in the bottle and has safely been capped	Safe transfer of the bottles into the creates	No
Transfer to creates	P. None C. None B. None P. None	No	The tomato sauce is already in the bottle and has safely been capped	The process is done carefully to prevent any damage to the bottles that may cause contamination. The process is done carefully to prevent any	No

Company Name:	**Firm A**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Bottle washing, sleeveing, labelling and printing	C. None B. None	No	The tomato sauce is already in the bottle and has safely been capped	damage to the bottles that may cause contamination.	No
Packing in box, storage in stores, pre-dispatch inspection and the dispatch.	P. None C. None B. None	No			No

Source: Field Survey, 2018

4.4 Hazard Analysis of Company B

For company B, its process flow diagram and corresponding Hazard Analysis Table (HAT) is shown in Figure 2. Company B is also located in Iringa with an area of 1,500 m^2 and that it is located more closely to tomato producing farmers than other companies considered for this study. This makes it easier for the farmers and the company to get the tomatoes to the factory. The fact that the company is located near the farmers, there is less spoilage that may be caused by long distance transportation of raw tomatoes.

The company receives its water from the municipal council locally but it has its water treatment plant in the compound. This treated water is used for both production and cleaning process. The inside and outside environment and the surrounding areas of the company were generally clean by the time of the field visit. The general hygiene of the production area is also very well taken care of.

4.4.1 Process Flow Chart

Figure 2, indicates a process flow diagram for company B. Unlike company A, it was made clear that, by the time of the fieldwork, company B was not HACCP certified. Also, it was noted that, although the basic components were witnessed to be in place, but its process flow diagram (which was constructed during the field survey) was, by the time of the field survey, less complex compared to that of company A.

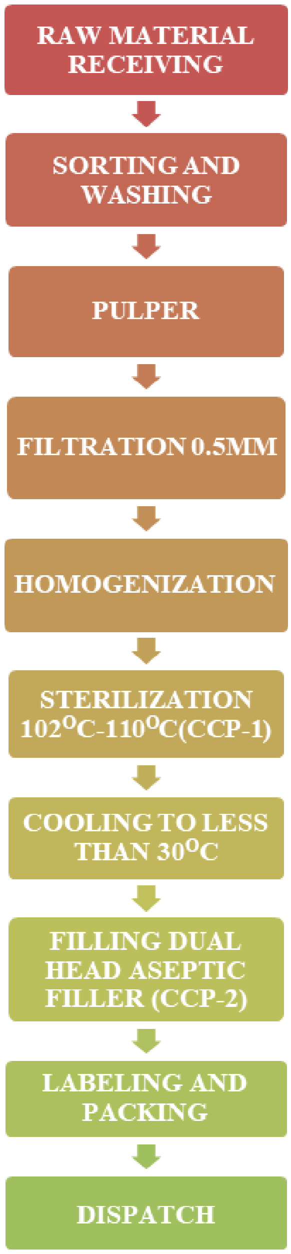

Figure 2: Process Flow Chart Diagram of Company B

Source: Researcher and Quality Control Personnel of Company B, 17/01/2020

4.4.2 Description of Process Flow Chart

In the raw material receiving area, there were clean plastic boxes used to receive the tomatoes that were being transferred from trucks in woven baskets. The company workers had to manually sort the tomatoes from well ripen to less ripen tomatoes. After the manual sorting, there is washing of the tomatoes with portable water from the water treatment plant. Washing of the tomatoes involved gentle but vigorous shaking of the fruits in water with disinfectant. From the washing basin, there is transfer of the clean tomatoes to the pulper. The pulper is made stainless steel which does not react with the product. The pulper does not have any signs of rust, it is in good condition and as per the production manager, it is checked regularly for maintenance. There is daily cleaning of the pulper and a weekly thorough cleaning. After pulping, the pulp is subjected to filtration in a sieve of 0.5mm. The sieve is also made of stainless steel which is rust free. After multiple productions, there are always some particles remaining in the sieve. This calls for thorough cleaning every after two production processes. This is done by removing the sieve and washing it with a scrubbing brush to ensure that all the particles that might be trapped are all removed. The filter is free from rust.

At the homogenization stage, there is addition of some ingredients. These ingredients are thoroughly checked and measured to ensure that there is no contamination and no deviations in the product quality. The product is then sterilized at $102^{O}C$ -$110^{O}C$. It is critically important to attain this temperature at this stage as it helps to kill all the microbes that might be present at this particular time. If this stage is not done properly then there is a possibility that there will be growth of microbes in the final product. After this process, the product is cooled and bottled in either plastic or glass bottles ready for dispatch. The plastic and glass bottles are usually aseptically stored to avoid any contamination. The bottle tops are also kept aseptically as they could also cause contamination. The filling is done in a well-protected area to ensure that the external environment does not contaminate the products. The filling is done automatically by the machines. The cleaning in place that is done regularly and weekly through cleaning.

4.4.3 Hazard Analysis Table for Company B

After working on the process flow diagram of company B, Hazard Analysis Table (HAT) of the same company is presented to show whether the control point is critical or not. Therefore, Table 4 below shows production, potential hazard identification and determination of the significance of the hazard, decision justification, preventive measures, and its control with respect of company B.

Table 4: Hazard Analysis Table for Company B

Company Name:	**Firm B**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Raw material receipt, Sorting and washing.	P. Presence of foreign matter from farm(grass, stones, pieces of broken wood from the boxes used to carry the raw tomatoes,)	None	There is sorting and sieving process down stream Pealing and washing reduces the levels to acceptable levels	Inspection of the raw materials Proper checking of CoA from suppliers	No No
	C. Agrochemical residue from farm, grease may be present from the trucks used for carrying the raw tomatoes	None	There is cooking and pasteurization later in processing	GMP and GHP	No

Company Name: **Firm B**		**Product Description:**	**Tomato sauce**		
Firm Address: **IRINGA**		**Method of storage and distribution:**	**Stored at room Temperature**		
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**		
Date:					
(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
	B. *Staphylococcus aureus, E. coli, Salmonella typhi* from the farmers and factory personnel	None			
Pulping and filtration (0.5 mm sieve)	P. Removal of tomato peels and pieces of grass and stones. C. None B. None	Yes	Failure of proper sieving could lead to physical hazards in the final product.	Ensure the size of the sieve is always 0.5mm	Yes
Mixing ingredients, homogenization and Sterilization 102^0C-110^0C	P. Introduction of foreign matter from ingredients and water	No	Obtain ingredients from approved suppliers, treatment	GMP	No

Company Name:	**Firm B**	**Product Description:**	**Tomato sauce**		
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**		
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**		
Date:					
(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
(CCP 2)	C. Ingredients B. *Staphylococcus aureus, E. coli* and coli forms from processing water	No No	of water to be used for processing There is cooking and pasteurization later in processing	GMP Water treatment and monitoring of the sterilization temperature.	No Yes
Cooling to less than 30^{0}C	P. None C. None B. None	No			
Filling dual head aseptic filler (CCP 3)	P. Dust particles from the cap and the bottle.	Yes	From poor storage of the packaging	Inspection of the packaging equipment.	Yes.

Company Name: **Firm B**		**Product Description:**		**Tomato sauce**	
Firm Address: **IRINGA**		**Method of storage and distribution:**		**Stored at room Temperature**	
Signature:		**Intended Use and Consumers:**		**Used as cooking spice and condiment**	
Date:					
(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
	C. None B. None		equipment.	Rinsing of the packaging material and doing aseptic packaging.	
Labelling and packaging	P. None C. None B. None	No			
Dispatch	P. None C. None B. None	No			

Source: Field Survey, 2018

4.5 Hazard Analysis for Company C

Company C is situated along Mbeya Road, Kibwabwa Industrial Area in Iringa region. By the time of the fieldwork, the company had 20 workers who are exclusively devoted in the processing of tomatoes. While the entire compound of the entire firm was estimated to be 4,000 m^2, approximately 2,000 m^2 of the said compound was designated for a plant of tomato processing. Such space, was expected to allow the company to have well-constructed structures (with appropriate space) to ensure a smooth production process and other related activities.

4.5.1 Process Flow Chart

As shown in Figure 3, after discussing with production manager of company C, it was established that the process flow diagram was less detailed. Partly, this could be explained by the fact that, by the time of the fieldwork, the said production manager, who worked in the production department of company C, was working mainly based on his experience as opposed to professional qualifications.

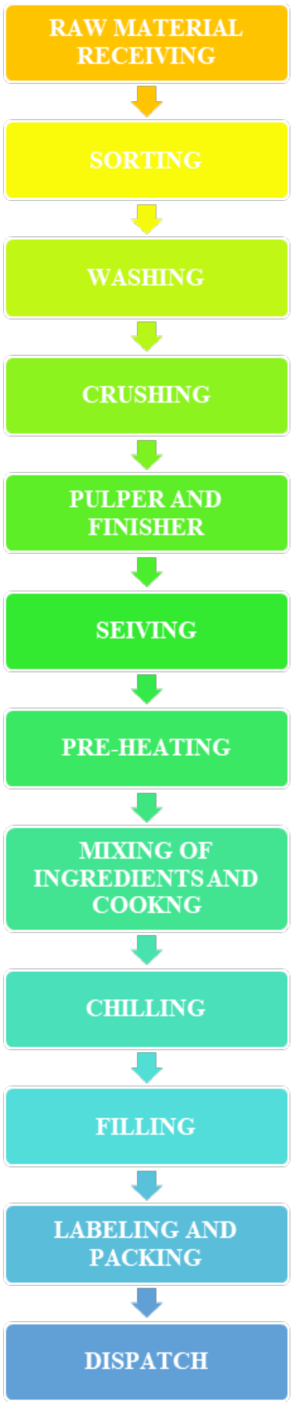

Figure 3: Process Flow Chart Diagram of Company C

Source: Researcher and Quality Control Manager of Company C, 18/01/2020

4.5.2 Description of process flow chart

As Figure 3 shows, though the process flow diagram is less detailed, yet it shows all basic components of tomato sauce production. This can be confirmed by all components, ranging from receiving the raw materials (mainly raw tomatoes) to dispatch of finished products at the end of the chart. During the receipt of the raw materials, the tomatoes were off-loaded from trucks and put into plastic drums before they were sorted manually by well protected company workers. Sorting was done on stainless steel covered tables that were often cleaned after the production process. Washing was done using portable treated water. There was thorough rinsing of the products before they were loaded into the crusher. Loading into the crusher was done automatically by conveyers that were connected to the crusher. The crusher was made of stainless-steel material which is easy to clean and does not rust. From the crusher, the puree was transferred to the pulper and finisher. The puree was then transferred to the sieve which was seen to be in good condition (that is, clean and rust free). After sieving, all the other ingredients are mixed together and cooked.

During the factory visit, it was observed that the workers adhered to hygienic practices as well as preheating of each intermediate product as way to reduce any potential contamination. However, during the factory visit, there were some discrepancies noted. For example, production environment was not good due to presence of cracked floor and direct communication between the outside and production environment. These had the potential to cause contamination.

4.5.3 Hazard Analysis Table for Company C

After describing the process flow diagram of company C, Table 5 presents the Hazard Analysis Table (HAT) of the same company. The HAT shows the production, potential hazard identification, determination of their significance, decision justification, possible preventive measures, and its control with respect of company C. In that regard, HAT indicates whether the control point is critical or not.

Table 5: Hazard Analysis Table for Company C

Company Name:	**Firm C**	**Product Description:**	**Tomato sauce**
Firm Address:	**IRINGA**	**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Raw material receipt, Sorting and washing	P. Presence of foreign matter from farm	No	There is sorting and sieving process down stream	Inspection of the raw materials	No
	C. Agrochemical residue from farm	No	Pealing and washing reduces the levels to acceptable levels	Proper checking of CoA from suppliers	No
	B. *Staphylococcus aureus, E. coli, Salmonella typhi* from the farmers and factory personnel	No	There is cooking and pasteurization later in processing	GMP and GHP	No

Company Name: Firm C **Firm Address:** IRINGA **Signature:** **Date:**		**Product Description:** Tomato sauce **Method of storage and distribution:** Stored at room Temperature **Intended Use and Consumers:** Used as cooking spice and condiment			
(1) Ingredients/Processing step	**(2) Identify potential hazards introduced, Controlled or enhanced at this step**	**(3) Are any potential food-safety hazards significant (YES/NO)**	**(4) Justify the decision for column 3**	**(5) What preventive critical measures can be applied to prevent the significant hazard**	**(6) Is this step a control point? (YES/NO).**
Pulping and finisher	P. Removal of tomato peels and pieces of grass and stones. C. None B. None	Yes	Failure of proper sieving could lead to physical hazards in the final product.	Ensure the size of the sieve is always 0.5mm	Yes
Mixing ingredients and cooking	P. Introduction of foreign matter from ingredients and water	No	Obtain ingredients from approved suppliers, treatment of water to be used for processing	GMP	No

Company Name: **Firm C** **Firm Address:** **IRINGA** **Signature:** **Date:**		**Product Description:** **Tomato sauce** **Method of storage and distribution:** **Stored at room Temperature** **Intended Use and Consumers:** **Used as cooking spice and condiment**			
(1) Ingredients/Processing step	**(2) Identify potential hazards introduced, Controlled or enhanced at this step**	**(3) Are any potential food-safety hazards significant (YES/NO)**	**(4) Justify the decision for column 3**	**(5) What preventive critical measures can be applied to prevent the significant hazard**	**(6) Is this step a control point? (YES/NO).**
	C. Ingredients B. *Staphylococcus aureus, E. coli* and coli forms from processing water	No No	There is cooking and pasteurization later in processing	GMP Water treatment and monitoring of the sterilization temperature.	No Yes
Chilling and filling	P. Dust particles from the cap and the bottle. C. None B. None	Yes	From poor storage of the packaging equipment.	Inspection of the packaging equipment. Rinsing of the packaging material and doing aseptic packaging.	Yes
Labelling and packaging	P. None C. None	No			

Company Name: **Firm C**		**Product Description:**	**Tomato sauce**
Firm Address: **IRINGA**		**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
	B. None				
Dispatch	P. None C. None B. None	No			

Source: Field Survey, 2018

4.6 Hazard Analysis for Company D

Company D is found in Dar es Salaam. During the field visit, the company had nearly 15 workers. The compound in which this plant is installed was relatively smaller (approximately 800 m^2) than areas of other companies under the study.

4.6.1 Process Flow Chart

Unlike the process flow diagrams of other sample companies (i.e., company A, B, and C), the process flow diagram of company D, which is shown in Figure 4, is the shortest. That is, along the process flow, it does not reveal production processes such as crushing, sieving (filtration), pre-heating, sterilization, and homogenization. A major reason behind this finding is that, by the time of the factory visit, it was revealed that company D operated those processes manually.

Figure 4: Process Flow Chart Diagram of Company D

Source: Researcher and Quality Control Manager of Company D, 18/01/2020

4.6.2 Description of Process Flow Chart

The raw materials are received from the nearest market in Temeke area (Temeke Sterio market). The tomatoes are always in wooden crates. After receiving the tomatoes from the market, they are sorted to remove the rotten and not well ripen fruits. All tomatoes are then put in a big plastic drum for washing. The drums were seen to be clean and they were cleaned every after a production process.

The water used is from a bore hole that has been dug in the company area. This water is well treated before being used in the production and cleaning process. After the cleaning process, the well washed tomatoes are put in a pulper and finisher which are in good condition and are clean. The pulp is then mixed with the rest of the ingredients and cooked. The ingredients are well kept in cool dry places after receiving which helps for them not to be contaminated. After cooking, the product is then cooled and filled in food grade cans, labeled and ready for dispatch.

Most of the processes along the process flow chart were undertaken manually. With such manual practices in place, one would anticipate potential contamination of tomato sauce. However, there was cooking process involved and the use of preservatives. Therefore, from the start, it was hypothesized that cooking and the use of preservatives would minimize the probability of contamination of the final product. This is one the reasons the final product (tomato sauce) of company D (as well as that of other sample companies) was subjected in the laboratory test for analysis of microbial and chemical contamination (the results and discussion of the same are provided for in Section 4.9 of this dissertation).

4.6.3 Hazard Analysis Table for Company D

Table 6 presents the Hazard Analysis Table (HAT) of the company D. The ultimate purpose of information contained in HAT is to understand whether the control point is critical or not. In this regard, the HAT shows the production, potential hazard identification, determination of their significance, decision justification, possible preventive measures, and establishment in respect of company D.

Table 6: Hazard Analysis Table for Company D

Company Name: **Firm D**		**Product Description:**	**Tomato sauce**
Firm Address: **DAR ES SALAAM**		**Method of storage and distribution:**	**Stored at room Temperature**
Signature:		**Intended Use and Consumers:**	**Used as cooking spice and condiment**
Date:			

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Raw material receipt, Sorting and washing	P. Presence of foreign matter from farm	No	There is sorting and sieving process down stream	Inspection of the raw materials	No
	C. Agrochemical residue from farm	No	Pealing and washing reduces the levels to acceptable levels	Proper checking of CoA from suppliers	No
	B. *Staphylococcus aureus, E. coli, Salmonella typhi* from the farmers and factory personnel	No	There is cooking and pasteurization later in processing	GMP and GHP	No

Company Name: **Firm D** **Product Description:** **Tomato sauce**

Firm Address: **DAR ES SALAAM** **Method of storage and distribution:** **Stored at room Temperature**

Signature: **Intended Use and Consumers:** **Used as cooking spice and condiment**

Date:

(1) **Ingredients/Processing step**	**(2)** **Identify potential hazards introduced, Controlled or enhanced at this step**	**(3)** **Are any potential food-safety hazards significant (YES/NO)**	**(4)** **Justify the decision for column 3**	**(5)** **What preventive critical measures can be applied to prevent the significant hazard**	**(6)** **Is this step a control point? (YES/NO).**
Pulping and finisher	P. Removal of tomato peels and pieces of grass and stones. C. None B. None	Yes	Failure of proper sieving could lead to physical hazards in the final product.	Ensure the size of the sieve is always 0.5mm	Yes
Mixing ingredients and cooking	P. Introduction of foreign matter from ingredients and water C. Ingredients	No No	Obtain ingredients from approved suppliers, treatment of water to be used for processing	GMP GMP	No No

Company Name:	**Firm D**	**Product Description:**		**Tomato sauce**	
Firm Address:	**DAR ES SALAAM**	**Method of storage and distribution:**		**Stored at room Temperature**	
Signature:		**Intended Use and Consumers:**		**Used as cooking spice and condiment**	
Date:					
(1) Ingredients/Processing step	**(2) Identify potential hazards introduced, Controlled or enhanced at this step**	**(3) Are any potential food-safety hazards significant (YES/NO)**	**(4) Justify the decision for column 3**	**(5) What preventive critical measures can be applied to prevent the significant hazard**	**(6) Is this step a control point? (YES/NO).**
	B. *Staphylococcus aureus, E. coli* and coli forms from processing water	No	There is cooking and pasteurization later in processing	Water treatment and monitoring of the sterilization temperature.	Yes
Chilling and filling	P. Dust particles from the cap and the bottle. C. None B. None	Yes	From poor storage of the packaging equipment.	Inspection of the packaging equipment. Rinsing of the packaging material and doing aseptic packaging.	Yes

Company Name: **Firm D** **Product Description:** **Tomato sauce**

Firm Address: **DAR ES SALAAM** **Method of storage and distribution:** **Stored at room Temperature**

Signature: **Intended Use and Consumers:** **Used as cooking spice and condiment**

Date:

(1) Ingredients/Processing step	**(2) Identify potential hazards introduced, Controlled or enhanced at this step**	**(3) Are any potential food-safety hazards significant (YES/NO)**	**(4) Justify the decision for column 3**	**(5) What preventive critical measures can be applied to prevent the significant hazard**	**(6) Is this step a control point? (YES/NO).**
Labelling and packaging	P. None C. None B. None	No			
Dispatch	P. None C. None B. None	No			

Source: Field Survey, 2018

4.7 Discussion of Hazard Analysis Table

After presenting and describing the process flow chart, which was followed by presentation of Hazard Analysis Table (HAT) for all companies covered in this study, the discussion of HAT is provided in this section.

The common thing that was observed in the HAT is that all the companies were very careful in the choice of the raw materials. The storage of all the materials was also properly done by all the companies in cool and clean storage places. The equipment used in the processing was seen to be in good condition and all the companies were really careful when it came to the cleaning processes of the equipment used in processing. Where temperatures were to be observed, the companies were careful to maintain them at the required temperatures. All the workers at the companies were kin when it came to wearing their protective clothes which were also seen to be clean most of the time. Generally, the company workers were aware of the FSQCPs. This helped to a greater extent to minimize product contamination during processing.

4.8 Quality Control Practices of Tomato Processing Firms

In this section, various quality control practices employed by the sample tomato sauce processing firms in the study areas are presented and discussed.

4.8.1 Specification of Raw Materials and Testing

The results on the specification of raw materials and testing are shown in Table 7. As shown in Table 7, all the four (100%) processing companies considered for this study had a specification for the raw materials. Also, all of them controlled the temperatures in rooms where the raw materials were stored before the processing begun.

Table 7: Raw materials specification and testing

Raw materials	Response	Frequency	Percent
Specification for raw materials checked	Yes	4	100
	No	0	00
	Total	4	100
Testing batches	Yes	2	50
	No	2	50
	Total	**4**	**100**
CoA checked to confirm compliance	Yes	0	0
	No	4	100
	Total	**4**	**100**
Temperature control of raw materials	Yes	4	100
	No	0	0
	Total	**4**	**100**

Source: Field Survey, 2018

For the final products to be of good quality, the raw materials are to be of satisfactory quality. A report by Salgueiro *et al.* (2010), control of the raw materials is a prerequisite for reliable products. All the companies in the sample (100%) did not check for the Certificate of Analysis (CoA), which, is a document issued by quality assurance office to confirm that a regulated product meets its product specification (Baker, 2013).

It was further observed that the companies did not check for CoA because they received raw materials (raw tomatoes) from different farmers every season. Indeed, two companies (50%) were seen to be checking the batches. The other two companies (50%) did not check for the batches of the incoming raw materials partly because they have established raw tomato collection points from various farm areas where tomatoes are produced.

4.8.2 Processing and Packaging

Table 8 shows compliance on stated parameters, they all checked for clean equipment before starting production process. This was done to ensure that there was no any physical and microbial contamination of the final product. In process condition was monitored by all the companies which helped to check for any temperature changes, pH, total solids and colour along the production line.

The management of non-conforming products was done by all the companies. The defects were either fixed or the non-conforming products removed from the production line. This is evidence that all the four companies were aware of the importance of the processes control during food processing. As reported by McFarlane (2013), it is important to control and monitor of the production process in food manufacturing. Indeed, process control in the food manufacturing industry ensures increased quality, reduced costs, and improved safety (Linko and Linko, 1998).

Also, Table 8 shows that all companies (100%) were seen to be using filtered and disinfected water. These results concur with those of Kirby *et al.* (2003) in Switzerland where water was seen to be a transmission vehicle for many disease-causing agents and therefore called for its treatment before use if food processing.

Table 8: Processing and Packaging

	Response	Percent	Frequency
Check for clean equipment before start process	Yes	4	100
	No	0	0
	Total	**4**	**100**
In process condition monitored	Yes	4	100
	No	0	0
	Total	**4**	**100**
Sample analysis during processing	Yes	4	100
	No	0	0
	Total	**4**	**100**
Sample analysis at the end of the processing	Yes	3	75
	No	1	25
	Total	**4**	**100**
Management of non-conforming products	Yes	4	100
	No	0	0
	Total	**4**	**100**
Filtering and disinfection of water	Yes	4	100
	No	0	0
	Total	**4**	**100**

Source: Field Survey, 2018

4.8.3 Packaging Materials

With regard to packaging materials, all the processing companies ensured that they had food grade packaging material (Table 9). It is a requirement for the food processing companies to ensure that the packaging material are of food quality and that the labeling is appropriate for the particular food (TFDA, 2012). All food packaging material should consist of a similar basic character. The materials used for food packaging should be one that has the ability to maintain the food quality and ensure food safety. Also, they should be able to prevent unfavorable factors for food contamination such as chemical contaminants, microbial spoilage, and oxygen (Rhim, *et al*, 2013).

Table 9: Packaging Materials

	Response	Percent	Frequency
Certified for food contact use	Yes	4	100
	No	0	0
	Total	**4**	**100**
Codes for each delivery of packaging material	Yes	2	50
	No	2	50
	Total	**4**	**100**
Quarantined until checked for approval	Yes	2	50
	No	2	50
	Total	**4**	**100**
Inspection of material before use	Yes	3	75
	No	1	25
	Total	**4**	**100**

Source: Field Survey, 2018

4.8.4 Layout of the Buildings

As shown by Imai (2012), an efficient layout of the building designed for factory operation is necessary for guaranteeing high productivity and product quality. Also, efficient factory layout, is one of the components of good production management practices (Bloom *et al*., 2013; Hosono, *et al*., 2020) to ensures good flow of various raw materials during the production process. This study explored if the sample tomato processing companies adopted the layout of the buildings.

Table 10 reveals that all the processing companies were seen to have no sources of contamination from the surroundings. Also, the ventilation and filtered air was proper for all the companies while at the same time the flow of personnel and materials was unidirectional (100%). This finding is in line with the study done by Hofstra *et al.* (1994)

that showed that safe processed food can be achieved by simply adopting a proper building layout of the food manufacturing plant.

However, only three companies (75%) had proper floors and walls of impervious material. This is a requirement to ensure that there is easy cleaning and minimal contamination of the food during processing while one (25%) had floors and walls that were not of impervious material. Two of the companies (50%) had no cracks on the walls and the floors while two of the companies (50%) had cracked walls and floors. The results reveal that no company (100%) had a proper maintenance plan for the plant.

Table 10: Building Layout

	Response	Percent	Frequency
Maintenance of plant	Yes	0	0
	No	4	100
	Total	**4**	**100**
Source of contamination from surrounding	Yes	0	0
	No	4	100
	Total	**4**	**100**
Ventilation and filtered air	Yes	4	100
	No	0	0
	Total	**4**	**100**
Floors & walls of impervious materials	Yes	3	75
	No	1	25
	Total	**4**	**100**
No cracks	Yes	2	50
	No	2	50
	Total	**4**	**100**
Flow of personnel and material unidirectional	Yes	4	100
	No	0	0
	Total	**4**	**100**

Source: Field Survey, 2018

4.8.5 Traceability

The study finds that all four companies (100%) retained samples of the raw materials to finished products (Table 11). Only three companies (75%) showed that they had proper and rapid feedback in place. Indeed, ISO 22005:2007 gives a comprehensive explanation of the principle and requirements for the design and implementation of feed and food traceability system. One company (25%) had no rapid and proper feedback in place. Only two companies (50%) had written procedures in place for traceability.

Table 11: Traceability

	Response	Percent	Frequency
Retain sample from raw materials to finished products	Yes	4	100
	No	0	0
	Total	**4**	**100**
Written procedures for traceability	Yes	2	50
	No	2	50
	Total	**4**	**100**
Proper feedback in place	Yes	3	75
	No	1	25
	Total	**4**	**100**
Rapid feedback available	Yes	3	75
	No	1	25
	Total	**4**	**100**

Source: Field Survey, 2018

4.8.6 Documentation

As indicated in Table 12 below, only one company (25%) was seen to have proper documentation of records for every procedure. The other three companies (75%) did not have documentation for the procedures. Two companies (50%) were seen to have the ability to rapidly identify the documents.

The above finding is suggestive evidence that some of the basic production management practices (e.g., documentation or rather, recordkeeping) among the sample tomato processing firms are not fully utilized. Indeed, the finding is consistent with a study by Bloom *et al.* (2013) and Sonobe and Otsuka (2014), who found that the vast majority of the manufacturing enterprises in India and sub-Saharan Africa (SSA) remain weak in adopting such useful practices, respectively.

Table 12: Documentation

	Response	Percent	Frequency
Documentation for every procedure	Yes	1	25
	No	3	75
	Total	**4**	**100**
Documents allow rapid identification	Yes	2	50
	No	2	50
	Total	**4**	**100**

Source: Field Survey, 2018

4.8.7 Availability of Personnel Designated for Quality Assurance

Table 13 shows that three of the companies (75%) had personnel in charge of quality assurance (QA). However, one company no QA personnel. The company hired staff to serve at as of QA. However, this person had no any training or qualification for the job.

Table 13: Personnel Designated for Quality Assurance

	Response	Percent	Frequency
Qualified for specific job	Yes	3	75
	No	1	25
	Total	**4**	**100**
Medical certificate	Yes	4	100
	No	0	0
	Total	**4**	**100**
Exempted when sick	Yes	3	75
	No	1	25
	Total	**4**	**100**
Toilet and hand washing facility	Yes	4	100
	No	0	0
	Total	**4**	**100**
Proper uniform	Yes	4	100
	No	0	0
	Total	**4**	**100**

Source: Field Survey, 2018

Moreover, the results indicate clearly that all the four companies (100%) have hand washing facilities at the toilets and the production area. Also, all four companies (100%) had the staff medically tested after every three months and to be having proper uniform. Only one company was seen to exempt its workers when they are sick. The rest of the three companies did not have proper arrangements of exemption from work when the workers were sick.

4.8.8 Training Experience

Training of workers is necessary for accumulation of hands-on skills required for efficient production and business manage (Bloom *at el*., 2013; Sonobe and Otsuka, 2014). Table 14 shows the results on the specific training experience in the four sample companies.

Table 14: Training Experience in the Tomato Processing Companies

	Response	Percent	Frequency
On job training	Yes	2	50
	No	2	50
	Total	**4**	**100**
Hygiene training frequently carried out	Yes	4	100
	No	0	0
	Total	**4**	**100**
Additional regular training	Yes	1	25
	No	3	75
	Total	**4**	**100**
Training on records keeping	Yes	1	25
	No	3	75
	Total	**4**	**100**

Source: Field Survey, 2018

The results on the specific training experience (Table 14) show that its only hygiene training that was frequently carried out by all the four companies (100%). Additional regular training and keeping of training records was only done by one company (25%). On the job training was only done by two companies (50%) while the other two (50%) did not do on the job training. On the job trainings and motivation is an important factor to help food handlers to put into practice the food handling skills that they have (Mulugeta *et al.*, 2012). This study is in line with the study done in Nigeria where food hander training was being associated with improved knowledge and behaviors of the food handlers (Hezekia *et al.*, 2015).

4.8.9 Cleaning

As indicated in Table 15, while three companies (75%) were seen to keep cleaning products in a separate store one company (25%) did not have a separate store for the cleaning products. This finding provides suggestive evidence that though basic cleaning is fundamental, yet this practice (by the time of the field survey) was passively given its due attention by some of the tomato processors in the sample.

Table 15: Cleaning

	Response	Percent	Frequency
Cleaning products in special store	Yes	3	75
	No	1	25
	Total	**4**	**100**

Source: Field Survey, 2018

4.9 Results of Microbial Pathogens and Pesticide Residues

The results related to the microbial pathogens and pesticide residuals are presented and discussed in sub-section 4.9.1 and 4.9.2, respectively.

4.9.1 Microbial pathogens

Table 16, show the results of microbial analysis of samples collected in the four firms, that is, the total number of colony forming units (CFU) counted in the dilution plates of 10^{-4}. The last dilution, which was 10^{-4}, had CFU less than the detectable limits (that is, a limit of <100 CFU).

The above finding may be explained by, among others, the fact that all the firms (100%) had sorting and washing and peeling processes at the receiving point of all the raw tomatoes. Actually, the existing literature suggests that washing processes reduces the initial bacterial counts tremendously and this results to good quality products (Keikotlhaile *et al*., 2010). After sorting, washing and peeling the raw tomatoes, thermal treatment follows in tomato processing. This may include drying, heating, and pasteurization. In the heat treatment processes, there is another reduction in the microbial load.

Nonetheless, food handlers can be a source of contamination in the food processing industry through poor personal hygiene or cross contamination. On the contrary, it was observed that all the visited firms (100%) manually handled the major raw materials (raw tomatoes) when washing and sorting only. The rest of the processes were automatically undertaken by machines invitro. Therefore, this practice partly explains such a CFU less than the detectable limits.

Table 16: Laboratory Results of Microbial Pathogens

	Company A	Company B	Company C	Company D	Acceptable Levels
Total Plate count (*N* = 40)	<100CFU/g	<100CFU/g	<100CFU/g	<100CFU/g	<100CFU/g
Staphyloccocus aureus (*N* = 40)	<100CFU/g	<100CFU/g	<100CFU/g	<100CFU/g	<100CFU/g
E.coli (*N* = 40)	ND	ND	ND	ND	NIL

Source: Laboratory Results, 2018

4.9.2 Pesticides Residue

Regarding pesticide residues, Lema *et al*. (2014) reports that the *Organochlorines*, *Organophosates*, and *Carbamates* are the three most commonly used pesticide groups in Tanzania. As the laboratory results revealed that there were no detected residues of any of such pesticide (that is, *Organochlorines*, *Organophosates*, and *Carbamates*) in the sample of tomato sauce collected in the four processing companies.

One could possibly inquire, “Why all the three pesticide residues were not detectable?” The possible reason to ascribe this finding is that during the fieldwork all the companies (100%) in the sample were observed to wash, peal, and cook the tomatoes during processing. Indeed, these undertakings are part of GMP. Hence, adoption of GMP was likely to lessen the existence of pesticide residues in the final product (tomato sauce). In fact, this explanation is consistent with Bajwa and Sandhu (2014) who found that the concentrations of pesticide residue in raw fruits and vegetables could potentially be reduced with handling and processing. Thus, adopting such practices like washing, pealing, blanching, and pasteurization reduces the pesticide levels by large amounts.

CHAPTER FIVE

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

It was noted that at the time of the field study, all but one of the companies were not HACCP certified. Despite this fact, even the companies that were not HACCP certified were seen to be seen to have knowledge and practice hazard analysis and prevention of food contamination. The companies had well-organized processes and they adhered to the practices related to HACCP.

Also, it was found that most of the components of FSQCPs were observed by the companies under study. While some practices behind FSQCP were adopted by 100%, other components of FSQCPs were not fully adopted by some of the companies.

Microbiological status indicated lower level than the accepted of contamination. Total number of colony forming units (CFU) counted in the dilution plates of 10^{-4} had less than the minimum threshold of detectable limits, that is, less than a limit of <100 cfu. Also, the pesticide residues, from pesticides which are commonly used by smallholder farmers (such as *Organochlorines*, *Organophosates*, and *Carbamates*) were not detected. Certainly, this empirical finding is suggestive evidence that processing of raw tomatoes and simultaneous application of GMP plays a major role in eliminating pesticide used in farming and reduction of microbial load in the final product (tomato sauce).

5.2 Recommendations

Based on the findings, the recommendations are as follows. First, even though the vast majority of the components of production process flow were found to be fairly undertaken by the companies yet, there is a need to continuously improve the same. This is especially important to do so amongst those processes which were found to be passively implemented.

Second, continuous formal training, especially to quality control personnel, is fundamentally essential for maintenance of a particular company's realization of safe products and cost-effective in the processing of tomato sauce. As part of regulatory activities, the government (through her designated regulating authorities) may consider designing and providing such training programs to small-scale food processing companies and tomato processors. It is broadly assumed that having a well-trained quality control personnel may be motivated to adopt FSQCPs. One of the primary objectives of establishment and existence of food regulatory authorities is that of inducing factory-level adoption of FSQCPs by food processing companies to reduce foodborne diseases and ensuring public health.

Third, since the findings suggest that the employed FSQPs have a potential to supress the levels of microbial load in tomato sauce and minimizes pesticide residues in the raw tomatoes, the firms are recommended to maintain (or even improve) the application of those practices. In so doing, those firms may potentially remain compliant to aspects of food hazards and sustain their competitiveness in the market.

The last recommendation is related to future research. That is, while the current study found a number of findings to add knowledge in the existing literature, still such findings point to the need of conducting more empirical studies, either in a similar or related food processing value chains in Tanzania. In so doing, more bottom up input shall be gathered to further contribute to our existing understanding of both technical and public policy issues for consideration.

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APPENDICE

Appendix 1. Questionnaire and Observation Checklist

Company Name	
Contact	
Date	

Question	Response
1.1. GENERAL	
1.1.1 General Information	
1.1.1.1 Is there evidence of a license to operate issued by the Regulatory Authority?	
[illegible] Is there a GMP related recalls from the market in last 2 years?	
2. PREMISES	
2.1 Are there any sources of environmental contamination in the area surrounding the building?	
2.2 If "YES", are protective measures undertaken?	
2.3 Are there physically separated areas for each production step?	
2.4 Is the flow of personnel and materials shown such that they are unidirectional& prevent product contamination &mix up?	
2.5 Is there packaging area completely physically separated from processing area?	
2.6 Is waste treatment program covering the entire factory?	
2.7 Is there a special lighting system in the sampling, weighing, processing area in case those photosensitive raw materials are being handled?	
2.8 Is there a laundry area for uniforms which is separate from production areas?	
3. CLEANING	
3.1 Is a validation performed to confirm major& minor cleaning effectiveness?	
3.2 Are there Validation Records?	
3.3 Is the Final Validation Report is supported by the signature of all those involved, the verification by Production and the signature of Quality Assurance?	

COMPANY INFORMATION

1.1. Name of Company: ....

1.2. Address of Company: ....

1.3. Type of Business: Manufacturing / Packaging only Contract manufacturer / Packer Marketing

1.4. No. of full-time employees: ....

1.5. No. of part-time / seasonal employees: ....

1.6. Are your company's premises registered for the manufacture and sale of food? Yes No

QUALITY MANAGEMENT

2.1. Is your company registered / registering for an accredited quality system, e.g. ISO? Yes No – If Yes, which? ....

2.2. Does the company have personnel specifically responsible for quality (e.g. Quality Control / Quality Assurance Manager)? Yes No

If Yes, are the authority and responsibilities of these personnel clearly defined? Yes No

2.3. Do these personnel have the authority to make independent decisions on product quality? Yes No

2.4. Is there documented evidence for all lots (batches) of product that demonstrates that all steps during manufacture are being carried out as per the defined procedures and that the quantity and quality produced are as expected? Yes No

2.5. Are reference samples retained of: – Starting materials? Yes No

Finished products in the final pack? Yes No

2.6. Are there procedures in place to ensure the traceability of all raw material, intermediate and finished product? Yes No

2.7. Do the traceability records allow for rapid identification of: – the suppliers of the raw materials Yes No – the complete manufacturing history of a lot of finished product Yes No – the businesses to which finished products have been supplied? Yes No

2.8. Is the information on traceability in a form that can be made available to the authorities on demand? Yes No

2.9. Is there a Supplier Quality Assurance procedure in place, laying down the criteria for selection, approval, review and ongoing approval, to ensure that the supplied products and services meet the expected requirements? Yes No

2.10. Are the Quality Assurance procedures of suppliers of raw and packaging materials monitored? Yes No

2.11. Is there a system in place allowing rapid feedback to the purchasing department if concerns are raised on the quality of purchased materials? Yes No

2.12. Is there a system in place allowing rapid feedback to the manufacturing department regarding modifications or corrective actions to be taken, if required? Yes No

2.13. Are summaries of quality performance data and advice (where relevant) regularly given to manufacturing personnel? Yes No

PERSONNEL AND TRAINING

Training

3.1. Is 'on the job' training given to personnel? Yes No

3.2. Are new employees given an induction course? Yes No

If Yes, does the course include hygiene training? Yes No

3.3. Is additional appropriate regular training offered to personnel? Yes No

3.4. For full time personnel, is their training subjected to formal review and assessment? Yes No

3.5. Are individual training records kept and maintained? Yes No

3.6. Have all relevant personnel who come into contact with raw materials / products, had training in basic food hygiene and hold the associated certification, where relevant? Yes No

3.7. Do office, maintenance and cleaning staff and any contractors who enter the production or storage areas receive food hygiene instructions? Yes No

3.8. Are all employees issued with a Company handbook which includes hygiene rules? Yes No

3.9. Is appropriate protective clothing provided to employees? Yes No

3.10. Is there a requirement for protective outerwear to be removed when leaving the manufacturing areas? Yes No

3.11. Are pre-employment medical checks carried out? Yes No

3.12. Are all visitors made aware of the Company's hygiene policy? Yes No

3.13. Is there a policy in place to ask visitors or contractors, before they enter any manufacturing areas, whether they have suffered or been in contact with any recent illness that may be a potential contamination risk to products? Yes No

3.14. Is there a reporting procedure for staff suffering from, or who are in close contact with people suffering from, specific medical conditions? Yes No

3.15. Is there a Personal Medication procedure in place? Yes No

3.16. Is there a Return to Work procedure in place following illness or holidays abroad? Yes No

3.17. Are there clear written policies in place: − on the wearing of wristwatches and jewellery in the manufacturing areas? Yes No

on items of clothing or jewellery that may be allowed in the manufacturing areas for medical, ethnic or religious reasons? Yes No on the wearing of make-up, associated items and perfumed products in the manufacturing areas? Yes No

on the carrying of loose items (pens, mobile phones etc.) in the manufacturing areas? Yes No

3.18. Are procedures in place for hand washing? Yes No

3.19. Is antibacterial cream, foam or gel available for applying after hand washing for personnel working in areas of high microbiological sensitivity? Yes No

PREMISES AND EQUIPMENT

Premises

4.1. Is there a Maintenance Plan that ensures the condition of buildings (both internal and external) and equipment is regularly reviewed and action taken when necessary? Yes No

4.2. Is there an Environmental Monitoring programme? Yes No

VENTILATION AND LIGHTING

4.3. Are manufacturing areas ventilated with a constant supply of appropriately filtered air? Yes No

4.4. Are there shatterproof covers on lights in the following areas:

raw material storage area? Yes No

manufacturing areas? Yes No

finished products storage area? Yes No

FLOORS, WALLS AND CEILINGS

4.5. Are the floors in the manufacturing areas made of an impervious and non-absorbent material? Yes No

4.6. Are they free from cracks and joints in areas where product is exposed? Yes No

4.7. Do drains have trapped gullies and proper ventilation? Yes No

4.8. Are any open drainage channels shallow and easy to clean? Yes No

4.9. Are walls intact and free of faults and finished with a smooth impervious and easily cleaned material? Yes No

4.10. Are windows made of toughened glass or plastic? Yes No

4.11. Are there fly screens on windows that open? Yes No

4.12. Do window ledges slope away from the glass at an angle to prevent items being placed on them? Yes No

4.13. Do doors have smooth, non-absorbent, easy to clean and disinfect surfaces? Yes No

4.14. Does the ceiling construction in manufacturing areas prevent the accumulation of dirt / growth of mould / shedding of particles? Yes No

FLOORS, WALLS AND CEILINGS

4.15. Is there a Site Hygiene Plan? Yes No

4.16. Are cleaning products stored in a location that is separate from the processing areas? Yes No

4.17. Is production waste collected in clearly identifiable receptacles for removal to specific collection points outside the buildings? Yes No

4.17. Is production waste removed from the manufacturing areas throughout the day? Yes No

4.18. How often is waste removed from the site? Daily Weekly

RECEIVING AND DISPATCH AREAS

4.19. Do the receiving and dispatch areas provide protection from the weather for materials or product in transit? Yes No

4.20. Is there a defined deboxing/debagging area for those materials which arrive in external packaging? Yes No

PERSONNEL HYGIENE FACILITIES

4.21. Are the following provided:

Changing facilities segregated from production area? Yes No

Toilet and hand washing facilities segregated from manufacturing areas? Yes No

Separate accommodation for clothing and footwear not being worn during working hours? Yes No

First Aid facilities and an accident book? Yes No

A rest and refreshment room segregated from production area, for recreation and eating? Yes No

4.22. Is the rest and refreshment room the only place where eating or drinking is allowed? Yes No

4.23. Is the whole site designated non-smoking? Yes No

PEST CONTROL

4.24. Is Pest Control practiced? Yes No

4.25. Is pest control contracted out? Yes No

If No, are there appropriate procedures in place for in-house pest control? Yes No

4.26. What steps are taken to protect against the entrance and harbouring of vermin, birds, pests and pets in all buildings on site? ....

EQUIPMENT

4.27. Are all surfaces and materials in contact with raw materials and finished product: −

Inert to the raw materials / product? Yes No

Microbiologically cleanable, smooth and non-porous? Yes No

Visible for inspection (or equipment is easily dismantled for inspection)? Yes No

Easily dismantled and readily accessible for cleaning? Yes No

4.28. Are there detailed cleaning procedures in place for all equipment? Yes No

4.29. Is all equipment cleaned and serviced immediately after use? Yes No

4.30. Are fumes from power driven equipment, heaters etc. ventilated away from the manufacturing areas? Yes No

4.31. Are there maintenance procedures in place for all equipment? Yes No

4.32. Is all equipment regularly serviced and calibrated? Yes No

If Yes, are appropriate records maintained? Yes No

Are these regularly checked to ensure calibration is up to date and equipment is working accurately? Yes No

4.33. Are there procedures in place outlining the action to be taken in the event of a recognised malfunction of the inspection and testing equipment? Yes No

WATER SUPPLY

4.34. Is the water supply monitored and controlled? Yes No

4.35. Is potable water used for all manufacturing purposes? Yes No

4.36. Is the water that is used for all manufacturing purposes periodically analysed,? Yes No

4.37. Where both potable and non-potable water are used on the premises, are the two water supplies clearly identified and kept separate from each other? Yes No

4.38. If the products being manufactured are vulnerable to microbiological contamination, are filtering or disinfection systems installed on the water supply? Yes No

PRODUCT DEVELOPMENT

Manufacture

5.1 Are all instructions and operating procedures clear and unambiguous and written in the official working language of the manufacturing facility? Yes No

5.2. Are periodic checks undertaken to ensure the Master Manufacturing Instructions are being followed and that they are still applicable and relevant? Yes No

Production

5.3. Prior to production commencing, are all materials, bulk containers and major items of equipment to be used indentified (e.g. labelled) with relevant information regarding the product to be processed? Yes No

5.4. Does the status label of the manufacturing area and equipment contain information regarding the previous product manufactured and the cleaning status when at rest? Yes No

Raw materials

5.5. Are detailed specifications held for all raw materials? Yes No

5.6. Are internal identification numbers allocated to all raw materials upon delivery? Yes No

5.7. Are raw materials entering the premises quarantined until they appropriately checked and a decision made on their status i.e. whether approved or rejected? Yes No

5.8. Are all raw material lots (batches) tested? Yes No

If No, specify what proportion are tested? ....

5.9. Are Certificates of Analysis (CoA) for raw materials checked to confirm compliance with the specifications? Yes No

If Yes, are periodic checks undertaken to verify the quality of the supplier's CoAs? Yes No

5.10. Are stocks of raw materials in the storage areas:

Inspected regularly? Yes No

Tested / sampled where appropriate? Yes No

5.11. Are the temperature and humidity for storing raw materials controlled and recorded? Yes No

5.12. Are there procedures in place for issuing raw materials from store? Yes No

5.13. Is correct stock rotation followed when issuing raw materials from store? Yes No

PACKAGING AND LABELLING MATERIALS

5.14. Are packaging materials certified for food contact use (i.e. in conformance with current legislation on materials and articles in contact with food)? Yes No

5.15 Is there a procedure in place to ensure that changes in product formulation are reflected in the label copy? Yes No

5.16. Are internal reference codes allocated to each delivery or lot/batch of packaging material? Yes No

5.17. Is packaging material entering the premises quarantined until it is appropriately checked and a decision made on its status i.e. whether approved or rejected? Yes No

5.18. Are stocks of packaging materials in store inspected regularly to check their condition? Yes No

5.19. Is stock rotation followed when issuing packaging materials from store? Yes No

5.20. Are all packaging materials inspected immediately before use? Yes No

5.21. Are procedures in place for:

the issue of packaging materials from store? Yes No

the return of part-used lots of packaging to store? Yes No

the re-sealing of part-used boxes of packaging, to prevent foreign body contamination? Yes No

the reconciliation of all printed packaging component stock from quantity issued, quantity used, wastage and that returned to store? Yes No

the removal and destruction of superseded packaging or labels? Yes No

PROCESSING AND PACKAGING

5.21. Are multiple packaging lines (where present) segregated to avoid the risk of cross-contamination? Yes No N/A

5.22. Are the following checks always carried out before the start of any process

The production area is clean and free from any items not relevant to the process to be undertaken? Yes No

Yes No − All plant and equipment is clean and ready for use? Yes No

5.23. Are in-process conditions monitored (e.g. by sensory, instrumental and / or laboratory testing) Yes No

5.24. Are samples analysed:

During production? Yes No

After production? Yes No

5.24. Are intermediate products quarantined until checked and approved by Quality Control? Yes No

5.25. Are packed finished products quarantined until checked and approved by Quality Control? Yes No

5.26. Are there procedures in place for the management of non-conforming products? Yes No

DISPOSAL OF WASTE AND EFFLUENT

5.26 Is the disposal of printed packaging materials, raw materials and reject product appropriately controlled? Yes No

5.27. Is reconciliation carried out on quantities of materials or product used and/or produced against those being disposed of? Yes No

5.28. Are all waste materials and effluent disposed of by a route appropriate to the class of material? Yes No

STORAGE

Access to storage areas

6.1. Is access to material and product storage areas restricted to those working in these areas and to other authorized persons? Yes No

6.2. Is there a formal list of persons who are authorised to access these areas? Yes No

6.3. Is there a suitable curtain at all entrances and exits of the storage area? Yes No

6.4. If the storage area connects to the manufacturing area, is a buffer area/pass box provided between the two areas? Yes No

Temperature and lighting

6.5. Is temperature mapping and recording carried out in the storage area(s)? Yes No

6.6. Do lighting appliances have shatterproof protective covers?   Yes   No

Materials and product storage

6.7. Is a stock rotation system followed? Yes   No

6.8. Are all aisles in the storage area(s) kept clear?   Yes   No

6.9. Are pallets regularly checked for structural integrity?   Yes   No

6.10. Are packed products stored in conditions necessary for safe storage, appropriate to their specifications?   Yes   No

6.11. Are stored materials and product clearly identifiable, even when stacked? Yes No

6.12. Is there a specific quarantine area for material deliveries / product batches awaiting results of testing?   Yes   No

Cleaning of storage areas

6.13. Are the storage facilities periodically inspected?

For cleanliness? Yes   No

For pest infestation? Yes   No

6.14. Are such inspections documented and any corrective actions noted?   Yes   No

6.15 Are there procedures in place for cleaning of the storage premises and equipment?

Yes   No