HYGIENIC DESIGN OF EQUIPMENT AND HYGIENE PRACTICES OF PROCESSORS AMONG THE MICRO AND SMALL ENTERPRISES IN THE SOFT DRINK INDUSTRY: CASE OF NAIROBI, KENYA

BY

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DEPARTMENT OF FOOD SCIENCE, NUTRITION AND TECHNOLOGY

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DECLARATION

I, **Naomi Jebichi Kitur,** hereby declare that this dissertation is my original work and that to the best of my knowledge it has not been presented for an award in any other institution.

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Kitur Naomi Jebichi Date

This dissertation has been submitted for examination with our approval as university supervisors.

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DEDICATION

I dedicate this work to my paternal grandfather, the late Abraham Chemaiyo Kitur Arap Sawe, for being a pacesetter in the pursuit of excellence and success in life, through sheer hard work, discipline and piety, and for instilling the same spirit in our young minds.

Special dedication to my parents Mr. Japheth Kitur and Mrs. Teresia Kitur for the selfless sacrifices they made in ensuring a solid foundation in the formative years of my life.

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LIST OF ACRONYMS AND ABBREVIATIONS

AAB – Acetic Acid Bacteria

AISI – American Iron and Steel Institute

BSc - Bachelor of Science

CFU – Coliform Forming Units

CGMP – Current Good Manufacturing Practices

CIP – Cleaning-In-Place

COP – Cleaning-out-of-place

CSLs - Critical Sampling Locations

GDP – Gross Domestic Product

EAC – East African Community

EAS – East African Standard

EC – European Council

EHEDG – European Hygienic Engineering and Design Group

EIA – Environmental Impact Assessment

EPS - Extracellular Polymeric Substances

FDA – Food and Drug Administration

GMP – Good Manufacturing Practices

GoK – Government of Kenya

ICMSF - International Commission on Microbiological Specification for Foods

ICN2 – Second International Conference on Nutrition

ISO – International Organisation for Standardization

KEBS – Kenya Bureau of Standards

KES – Kenya Shillings

KIPI – Kenya Industrial Property Institute

KIRDI – Kenya Industrial Research and Development Institute

KNBS – Kenya National Bureau of Statistics

KRA – Kenya Revenue Authority

KS – Kenya Standard

LAB – Lactic Acid Bacteria

MSEs – Micro and Small Enterprises

MSMEs – Micro and Small Enterprises

NEMA – National Environment Management Authority

NPS – National Police Service

QA – Quality Assurance

QAM – Quality Assurance Manager

QC – Quality Control

RO – Reverse Osmosis

RTE – Ready-to-eat

SANAS – South African National Accreditation Service

SML – Surface Microbial Load

SPSS - Statistical Packages for Social Sciences

SSOP – Sanitation Standard Operating Procedures

TS – Technical Specification

TSB – Tryptose Soya Broth

TVC – Total Viable Count

UK – United Kingdom

US – United States

WHO – World Health Organization

LIST OF DEFINITIONS

Biofilm – A convergence of microbial cells that are attached to a surface and enclosed in a film of protective extracellular polymers.

Cordials – A syrup concentrated drink which has to be diluted to a minimum ration of one to three, to produce a suitable drink after dilution and is obtained by blending clarified fruit juice with nutritive and/or non-nutritive (intense) sweeteners and water.

Fruit based soft drink - Unfermented product obtained by blending fruit juice (concentrated or unconcentrated) derived from fruit with not less than 10 % of soluble solids, with or without addition of nutritive and/or non-nutritive sweeteners, water and preserved by suitable preservative means.

Fruit flavoured drink - Concentrated or ready-to-drink products prepared from water and with additives such as sweetening agents, flavorings and colourants.

Fruit juice - Fruit juice is the unfermented but fermentable liquid obtained from the edible part of sound, appropriately mature, ripe and fresh fruit or of fruit and is fresh or preserved by chilling of one or mixed different types mixed together.

Micro enterprises – Companies with less than 10 employees, annual turnover of less than 500,000 Kenya shillings and with a registered plant investment capital of less than 10 million Kenya shillings.

Small enterprises - Companies with between 10 and 50 employees, annual turnover of between 500,000 and 5 million Kenya shillings, with a registered plant investment capital of between 10 and 50 million Kenya shillings.

Soft drinks - Non-alcoholic beverages, carbonated or not, containing natural or artificial sweeteners and other additives such as flavors, colors, acidulants, stabilizers, preservatives and sometimes fruit juice or comminuted fruit.

ABSTRACT

A number of food borne disease outbreaks globally are associated with biofilms, which is considered an emergent public health concern. Biofilms have become a problem within food industries as it causes surfaces inhabited to be resistant to effective cleaning and sanitizing. Colonization of equipment surfaces by bacteria and subsequent biofilm formation can be sources of cross contamination during food processing, leading to the lowering of product quality and predisposing consumers to possible pathogenesis.

This study was designed to evaluate the status of compliance of processing equipment used by Micro and Small Enterprises in the soft drink industry in Nairobi Kenya, to the European Hygienic Engineering and Design Group (EHEDG) criteria. Equipment cleaning regimes and the hygiene practices in these enterprises, and the post-cleaning microbial accumulation in the processing equipment were also assessed.

A checklist based on the EHEDG criteria and semi-structured questionnaires were administered to the enterprises. Face to face interviews were carried out with personnel in charge of production and quality control, as well as physical observation of the hygienic design status of the equipment. Microbial swabbing was carried out on food contact surfaces and hand swabs of personnel using horizontal methods according to ISO 18593: 2004, and samples analysed for selected microorganisms using standardized analytical methods based on International Organization for Standardization (ISO) standards. The data obtained was analysed using SPSS version 20 (SPSS Inc.) and results presented using Microsoft Office Excel 2010.

Majority of the sampled enterprises did not comply with the hygienic design criteria at 48%, compared with those who complied at 36%. Similarly, the cleaning regimes of majority of the enterprises (56%), involved Cleaning-Out-of-Place (COP) using manual methods with either

liquid soap or powdered multi-purpose soap as the main aids. Verification of cleaning and sanitizing effectiveness was only carried out by 6% of the enterprises through analysis of swabs or rinses for residual microorganisms or detergents.

Hygiene of the equipment and personnel were evaluated using microbial contamination of *Escherichia.coli*, *Staphyloccocus aureus, Pseudomonas aeruginosa, Listeria monocytogenes*, coliforms, Total Viable Count and *Enterobacteriacea.*

Escherichia coli was detected in the hands of one food handler at one of the enterprises and *Staphyloccus aureus* in the hands of one food handler at another. This was indicative of poor personnel hygiene practices and a potential source of cross-contamination to the equipment and food products. *Escherichia coli* was also detected in food contact surfaces (processing equipment) in eight of the enterprises with *Pseudomonas aeruginosa* being detected on the surfaces of equipment of three enterprises. While *Listeria monocytogenes* was not detected in any of the enterprises, 88%, 71% and 71% had Total Viable Counts, *Enterobacteriaceae* and coliform counts above the recommended levels respectively.

Majority of Micro and Small Enterprises in the soft drink subsector use processing equipment that do not comply with the hygienic design criteria. The cleaning and sanitizing regimes employed by the majority of these enterprises are also not adequate to ensure food safety. The regimes do not follow the recommended procedures for effective cleaning.

The study concludes that the status of hygienic design considerations of processing equipment and the hygiene practices among the processors within the Micro and Small category of enterprises in the soft drink industry are low. This leads to ineffective cleaning and sanitizing, and possibility of contamination of the products with hazardous microorganisms from the equipment and personnel.

The study recommends extensive creation of awareness of hygienic design requirements of food processing equipment among the food industry stakeholders, training of personnel in Micro and Small Enterprises to improve hygiene practices and enhanced local authority inspections, to ensure food safety.

CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND INFORMATION

According to the World Health Organization (WHO) (2015), the effects of food borne diseases are significant and affect entire populations in the world. The effects are pronounced within the low income sub regions and especially children aged between 0 and 5 years of age. Most cases of foodborne illness are a result of consumption of pathogens with food. The pathogens may not necessarily at the same time cause undesirable changes in food but mainly result in unsafe food without any signs of spoilage (Ward & Ward, 2015).

Microbial contamination of foods can occur along the value chain during production, processing, distribution and preparation for consumption. During processing, one of the main sources of microbial contamination is the equipment.

Hygienic design of equipment and hygienic practices are key factors in producing safe and wholesome food as it prevents contamination of products with hazards, specifically pathogenic microorganisms (Holan, 2000). To overcome different environmental stresses such as P^H, temperature and oxygen tension among others, bacteria form biofilms (Chadha, 2014). According to Brooks & Flint (2008), the primary advantages of biofilms formation to the microorganisms include utilization of potential benefits of a microbial community, defense against harmful conditions of antibiotics, detergents and sanitizers, and colonization of favorable niches.

Hygienic considerations are made during design of equipment to prevent biofilm formation because this ensures ease of effective cleaning and sanitizing to control microbial residues in equipment (Tamime, 2009). Deficiencies in equipment design combined with poor hygiene practice in processing may render the cleaning and disinfection ineffective (Simo˜es, Simo˜es, & Vieira, 2010), resulting in cross-contamination of food.

More than 90% of firms outside the agricultural sector in developing countries are Micro and Small Enterprises (MSEs) who constitute significant contributors to the development of the national economies (Muchina *et al.,* 2011). The MSE sector in Kenya comprises of two main sub-sectors: manufacturing and trade, with the majority of enterprises engaging substantially in agro-based activities and contribute significantly to production of goods and services to a large population in the society (Ong'olo *et al.,* 2013).The Kenya Vision 2030 initiative has seen an upsurge of MSEs in the recent years and as a result, the number of players in the manufacturing industry, specifically the food processing sector has increased.

Although the government has made efforts by developing a regulatory framework to guide and accelerate the growth of this sector, a study by Ngui (2014) indicates that innovation, financial constraints, regular information exchange mechanisms among institutions and most importantly research capacity are some of the challenges faced by the Micro and Small enterprises. These challenges largely affect the choice of processing equipment used for processing, which have an implication on the effectiveness of cleaning and sanitizing, hence compromising food safety. It is also possible that the work force in the MSES comprise mainly persons of low education and this makes the hygiene legislation difficult to implement.

In Kenya, about 80% of food products supplied to the domestic market are from the informal sector. As a result of rudimentary hygiene controls, diseases associated with food continue to be a major (Oloo, 2010).

1.2 STATEMENT OF THE PROBLEM

A number of food borne disease outbreaks globally are associated with biofilms, which is considered an emergent public health concern. Biofilms have become a problem within food industries as it causes surfaces inhabited to be resistant to effective cleaning and sanitizing (Srey *et al.*, 2013). Colonization of equipment surfaces by bacteria and subsequent biofilm formation can be sources of cross contamination during food processing (Schlisselberg & Yaron, 2013), leading to the lowering of product quality and predisposing consumers to possible pathogenesis. Depending on the equipment designs, the areas amenable to microbial habitation and biofilm accumulation include joints, crevices, cracks, valves, dead ends, corners and gaskets (Chmielewski & Frank, 2006). Such defects in the equipment provide protective microbial niches where these microorganisms survive cleaning and disinfection (Lindsay & Flint, 2009). Hygienically designed equipment is therefore a prerequisite for an efficient and effective cleaning and disinfection program (Simo˜es, Simo˜es, & Vieira, 2010).

Soft drinks are normally of the low-high acid category. They are therefore not likely to support the spore forming bacteria eminent in the non-acid foods. The fungi that can survive the high acidity are the only organisms of importance and they are likely to effect alcoholic fermentation in the anaerobic conditions of the product to compromise the quality. Moreover some of the aciduric bacteria which survive inadequate pasteurization could be pathogenic and their biofilms on the equipment surface could cross contaminate the products and multiply to cause illness.

Due to possible limitation in investment capital and technical capacity, the Micro and Small Enterprises (MSEs) are likely to use equipment which is either improvised or is locally fabricated, without the standard hygienic design considerations. The cleaning and sanitizing regimes applied are also not elaborate enough to adequately eliminate microorganisms and their biofilms. This problem is exacerbated by employment in processing of low technical competency.

1.3 STUDY JUSTIFICATION

The role of governments in ensuring food safety and quality was underscored during the Second International Conference on Nutrition (ICN2) in Rome Italy in November 2014. Governments play a key role in developing policies and regulatory frameworks, and establishing and implementing effective food safety systems that ensure food producers and suppliers throughout the food chain operate responsibly to supply safe and quality foods to consumers. There is need for use of hygienically designed equipment to prevent or minimise cross-contamination of food during processing. The findings of this study will therefore be beneficial in providing information on the status of microbiological safety of processing equipment among the Micro and Small Enterprises in the food industry, in relation to the hygienic design. This will subsequently assist in the formulation of policies that guide in the design and selection of appropriate processing equipment for use by MSEs.

Manufacturers of food processing equipment and food processors will gain insight into the need for hygienic design and selection and the practice of hygiene in the industry. The findings will also add to the body of knowledge and open up research in the area of food engineering, in Kenya.

1.4. STUDY OBJECTIVES

1.4.1. General Objective:

To assess the hygienic consideration in the design and selection of equipment, and the practice of hygiene by processors in the Micro and Small Enterprises in the soft drink industry in Nairobi metropolis.

1.4.2. Specific Objectives:

1. To establish the characteristics and product diversification of the Micro and Small Enterprises in the soft drink industry in Nairobi metropolis.

2. To establish the hygienic design and considerations during selection of processing equipment by the Micro and Small Enterprises in the soft drink Industry in Nairobi metropolis.

3. To evaluate the equipment cleaning regimes and the hygiene practices by the Micro and Small Enterprises in the Soft drink Industry in Nairobi metropolis.

4. To determine the post-cleaning microbial accumulation in the processing equipment used by Micro and Small Enterprises in the soft drink industry in Nairobi metropolis.

1.5 HYPOTHESES

1. The Micro and Small Enterprises in the soft drink industry in Nairobi metropolis are of varying characteristics and process diversified products.
2. The Micro and Small enterprises in the soft drink industry in Nairobi metropolis do not comply with the hygienic design considerations during selection of processing equipment.
3. The cleaning regimes employed by the Micro and Small Enterprises in the soft drink industry in Nairobi metropolis do not conform to the accepted equipment cleaning best practices.
4. The extent of post-cleaning microbial accumulation in the processing equipment used by Micro and Small Enterprises in the soft drink industry in Nairobi metropolis is above the acceptable limits.

CHAPTER TWO: LITERATURE REVIEW

2.1 THE KENYAN FOOD PROCESSING INDUSTRY: CLASSIFICATION AND COMPOSITION OF MICRO AND SMALL ENTERPRISES

In Kenya, about 80% of food products supplied to the domestic market are from the informal sector (Oloo, 2010). More than 90% of firms outside the agricultural sector are Micro, Small and Medium Enterprises (MSME's) who are significant contributors to the production of goods and services to a larger population in the society (Muchina *et al.,* 2011; Ong'olo *et al.,* 2013). The MSMEs sector in Kenya comprises of two main sub-sectors: manufacturing and trade. A wide range of products, including soft drinks and fruit juice, fall under the category of some of the products channeled into the market by the Micro and Small enterprises.

The definition of Micro and Small Enterprises differs from country to country and largely dependent on the economic structure of individual countries. (Ong'olo & Awino, 2013). In Kenya, the regulatory and institutional framework for the MSMEs is based on the company's annual turnover, number of employees and the investment in plant and machinery or registered capital as provided for in the Micro and Small Enterprises Act of 2012 (GoK, 2012) as shown in the table below:

Table 2.1: Micro and Small Enterprises

Entity	**No. of Employees**	**Annual Turnover**	**Plant Investment/Registered Capital**
Micro Enterprises	Less than 10	Less than KES. 500, 000	Less than KES 10M
Small Enterprises	10 – 50	KES. 500,000 – 5M	KES. 10M – 50M

(Government of Kenya, 2006-2010)(GoK, 2012)

More than 90% of firms outside the agricultural sector in developing countries are Micro, Small and Medium Enterprises (MSMEs) who largely contribute to the Gross Domestic Product (GDP) (Muchina *et al.,* 2011). The Kenya Vision 2030 initiative has seen an upsurge of MSMEs in the recent years, resulting in the rise in number of players in the manufacturing industry, specifically the food processing sector.

The Micro and Small enterprises sector in Kenya comprises of both trade and manufacturing sub-sectors, who engage substantially in activities that are based on agriculture and contribute significantly to production of goods and services to a larger population in the society (Ong'olo *et al.,* 2013) including food products. 80% of the products supplied to the domestic markets are from this sector (Oloo, 2010).

Despite the efforts of the Kenyan government in developing a legal and regulatory framework to guide and accelerate the growth of the Micro and Small enterprises, a study by Ngui (2014) indicates that innovation, financial constraints, regular information exchange mechanisms among institutions and most importantly research capacity are some of the challenges faced by the sector. As a result of the challenges, choice and selection of hygienic processing equipment and hygiene practices in manufacturing are likely to be compromised.

2.2 THE SOFT DRINK INDUSTRY

Soft drinks are non-alcoholic beverages, carbonated or not, containing natural or artificial sweeteners and other additives such as flavors, colors, acidulants, stabilizers, preservatives and sometimes fruit juice or comminuted fruit (Mise *et al.,* 2013; Ashurst, 2011). There are different categories of soft drinks based on the contents which include fruit juice, fruit drinks, cordials, carbonated beverages and fruit flavoured drinks among others. Fruit juice is an unfermented product obtained from sound and ripe fruit and is fresh or preserved by chilling of one or mixed different types mixed together (Ryan, 2014). Kenya standard specification for fruit drinks and squashes, KS 224: 2018, defines a fruit cordial as a syrup concentrated drink which has to be diluted to a minimum ration of one to three, to produce a suitable drink after dilution and is obtained by blending clarified fruit juice with nutritive and/or non-nutritive (intense) sweeteners and water. Fruit based soft drink is defined as an unfermented but fermentable product obtained by blending fruit juice (concentrated or unconcentrated) derived from fruit with not less than 10 % of soluble solids, with or without addition of nutritive and/or non-nutritive sweeteners, water and preserved by suitable preservative means. On the other hand, Kenya standard specification for water-based flavoured drinks, KS 1485: 2018 defines fruit flavored drink as a concentrated or ready-to-drink product prepared from water and with additives such as sweetening agents, flavorings and colourants.

Consumption of sugar sweetened beverages such as soft drinks, has significantly increased worldwide and are consumed by a wide range of the population, with children and the youth predominantly forming the largest population of consumers (Colchero *et al.,* 2015). This is attributed to high prevalence of marketing and advertisement targeted at children and adolescents (Temple & Alp, 2016). The products, especially fruit juices, are susceptible to microbial spoilage and may support pathogenic microorganisms which subsequently leads to evident chemical and physical changes with rapid deterioration, more so if the product is not pasteurized (Ashurst, 2011). The drinks have been categorized and defined by various standards such as Kenya and East African into cordials, nectars, fruit based soft drinks, fruit flavoured drinks, juices, juice & dairy blends and carbonated drinks. Carbonated soft drinks are defined by the East African Standard Specification for Carbonated Beverages (Soft drinks), EAS 29: 2000 ICS 67.100.01 as non-alcoholic beverages containing dissolved carbon dioxide, prepared using potable water with with or without one or more of the following ingredients: fruit juice, fruit pulp, vegetable extracts, flavouring materials, colourants, sweetening agents, acidulants, clouding matter and preservatives (EAC, 2000).

2.3 MICROORGANISMS IMPORTANT IN THE SOFT DRINK AND BEVERAGE INDUSTRY

Microbial contamination of beverage and soft drinks originate from the production process including the environment surrounding the industry, the raw materials, microbiological status of the equipment used and packaging materials, improper handling practices among other factors (Park & Chen, 2009). Soft drinks are rich in minerals and vitamins and contain high water activity levels rendering them susceptible to attack by microorganism (Stratford, 2006).

***Yeasts*:** Yeasts are the primary spoilage microorganisms in carbonated drinks since they are able to resist carbonation and high acidity of the drinks (Kregiel, 2015). Yeast produces ethanol as a result of fermentation which may exceed the recommended limit for non-alcoholic beverages (Riikka *et al.,* 2011). Some yeast has been shown to serve as indicators of poor hygiene during production even though they do not result in spoilage of the final products. They predominate the soft drink industries, are found on surfaces and places that are difficult to clean and disinfect and they include *Sporobolomyces*, *Rhodotororula, Aureobasidium* and *Sporidiobolus* (Stratford, 2006).

***Molds*:** Molds contamination of soft drinks occurs as a result of poor hygiene or contaminated packages during manufacturing and their basic growth conditions in soft drinks are availability of water and high acidity (Kregiel, 2015). Molds require oxygen for their growth unlike yeasts although some can grow at very low oxygen concentrations. The spores of molds are not able to grow in carbonated beverages but they can survive. Some of the molds isolated in soft drinks and in industry establishments are *Fusarium*, *Penicillium,* *Aspergillus*, *Rhizopus* and *Cladosporium* (Sarlin *et al.*, 2005). Fungal contamination often results in the production of toxins such as mycotoxins that are harmful to humans when ingested (Riikka *et al.*, 2011).

Bacteria**:** The growth of spoilage bacteria in soft drinks is due to their ability to tolerate high acidity present in soft drinks. Lactic acid bacteria (LAB) are microaerophilic, can grow in soft drinks containing fruit juices and they originate from juice ingredients, raw materials or from the packaging materials (Taskila & Ojamo, 2013). The most common LAB causing spoilage are *L. perolens*, *Leuconostoc mesenteroides*, *L. plantarum*, *Weissela confusa*, *L. paracasei*, *L. buchneri* and *L. brevis*. These microorganisms catabolize sugar leading to the formation of metabolites which are responsible for the increased astringency in soft drinks (Patel *et al.*, 2012).

Acetic acid bacteria (AAB) are aerobic and acid tolerant that grow at a pH of less than 3.8 and produces ketones acetic and acetaldehyde (Kregiel *et al.*, 2012). The presence of AAB in food processing environments at high numbers is an indicator of poor hygiene. These microorganisms are able to form biofilms on food processing surfaces or on packaging materials (Suzuki *et al.*, 2010). Their growth in soft drinks leads to package swelling, haze or sediments and flavor changes. The most commonly found belong to the genera, *Gluconobacter*, *Asaia* and *Acetobacter* (Kregiel, 2013).

Pathogenic bacteria have been found in high numbers in soft drinks due to poor hygiene. These microorganisms can survive acidic conditions of soft drinks although they cannot grow during storage. Pathogenic bacteria commonly found in soft drinks outbreaks include *Salmonella* and shiga-like toxin producing *Escherichia coli* which have been shown to survive for long in the drinks (Akond *et al.*, 2009). Spore-forming bacteria such as

Clostridium and *Bacillus* are inhibited in soft drinks due to the high acidity. However, their spores may remain viable in such products. Anaerobic *Clostridium butyricum* and *Clostridium sporogenes* are known to cause spoilage during syrup manufacture leading to off-flavors in the final products.

2.4 IMPORTANCE OF HYGIENE CONSIDERATION IN THE DESIGN AND SELECTION OF FOOD PROCESSING EQUIPMENT

Food processing equipment design has been indicated as one of the critical food safety issues in food processing plants by the US Food and Drug Administration (FDA) (López-Gómez *et al.,* 2013). Sanitary designs prevents cross-contamination by preventing harboring of hazards in equipment such as spoilage and pathogenic microorganisms, chemical residues, and physical contaminants (Holah, 2000). Cross-contamination from processing equipment occurs either from transfer points, food contact surfaces or microbial growth niches (Bilgili, 2006).

Generally, materials used in construction of the equipment should be hygienic, homogenous, resistant to chemicals, inert, physically durable, easy to maintain, and mechanically stable (Moerman & Kastelein, 2013). A study on stainless steel surface topography found that equipment surfaces have a potential to harbor bacterial cells and are hard to clean if they have high peaks and cracks, suggesting that surface finish is an important factor in food processing equipment (Schlisselberg & Yaron, 2013). Surfaces of materials selected for constructing food processing equipment should have micro topography characteristics that allow effective cleaning and sanitizing (Silva, Careli, Lima, & Andrade, 2010). The materials must be inert to the product during the prevailing processing conditions, mechanically stable and therefore resistant to tear and wear, corrosion resistant and non-toxic, and be inert to detergents and disinfectants (Lewan & Partington, 2014).

In addition to surface finish and material types, several other factors are considered during design and selection of food processing equipment. They include type of use of the equipment, level of cleaning and inspection, product to be processed in relation to microbiological risk, and degree of further product processing (Lelieveld *et al.,* 2014). Construction, geometry and self-draining ability of equipment (López-Gómez *et al.,* 2013) are also taken into account during the design. All product-contact surfaces should be self-draining to prevent accumulation of residues from processing and cleaning processes. The surfaces should also be easily accessible for effective cleaning and inspection (Nikoleiski, 2015). Difficult to clean equipment requires more severe cleaning procedures and lengthened duration of cleaning, resulting in increased costs, shorter equipment life, increased effluent discharge and reduced availability of the equipment for use in production (Costa *et al.,* 2013).

Selection of materials for construction of processing equipment has significant implication on the economic, operational and maintenance costs (Saravacos *et al.,* 2002), therefore impacting on the cost of purchasing of equipment meeting the hygienic design standards.

2.5 TYPES OF CLEANING AND SANITIZING SYSTEMS FOR FOOD PROCESSING EQUIPMENT IN THE SOFT DRINK AND BEVERAGE INDUSTRY

Successful cleaning of food processing equipment involves complete removal of remains of product, dirt and debris, and microorganisms using specified detergents, under specified conditions (Schmidt, 2012,Gibson *et al.,* 1999) such as temperature and time of contact, which determine the efficacy of the products (Taylor *et al.,* 1999). Sanitation Standard Operating Procedures (SSOP) vary from one processor to another (Goode *et al.,* 2013). However, the recommended procedure for cleaning and sanitizing food contact surfaces is rinsing, cleaning, rinsing again and finally sanitizing (Lindsay & Flint, 2009).

Cleaning generally occurs in stages. The soil and surfaces are wetted with the cleaning agent usually in aqueous mixture or solution, the cleaning agent is usually a chemical, which when wetted binds and dislodges the soil, obviates re-deposition of soil and finally disinfects to remove any residual microorganisms (Gibson *et al.,* 1999).

According to Thomas & Sathian (2014), specification of the appropriate time transpiring between the processing and the cleaning of the equipment is important to prevent surface fouling of the equipment, which may lead to growth of pathogenic thermophilic bacteria. Microbial fouling or biofouling occurs when living microorganisms and their decomposition products form undesirable layers on surfaces in contact with liquid media (Kumar & Anand, 1998). Evans *et al.,* (2004) states that the microbial load on food contact surfaces varies from one food plant to another, depending on the microbiological quality of the food processed and the cleaning regimes in place. Gibson *et al.,* (1999) found that cleaning reduces the microbial load from these surfaces. However, the study revealed that the microbial residue was still in significant quantities even after cleaning, indicating that disinfection post-cleaning is critical. This was further demonstrated by Akiyama *et al.,* (1999), who showed that use of 2.5% acetic acid reduced the colony counts of *Staphylococcus aureus* by over 100 times, in a study to assess the antimicrobial effects of the acid on multiplication rate and immature buildup of biofilms of the organism.

There are two cleaning processes of processing equipment in the food industry: Cleaning-In-Place (CIP) and Cleaning-Out-of-Place (COP) (Matuszek, 2013). In CIP, solutions of alkaline and acid cleaners and sanitizers circulating under high velocity are used (Goff, 2007). Equipment is cleaned *in situ* and treatment usually carried out using hot solutions, although cold solutions can be used for fat-free products (Salo *et al.,* 2005). The effectiveness and completeness of the CIP process is based on prior determination of the amount of cleaning liquid and the temperature that will effect successful cleaning of the equipment. In COP, equipment is dismantled and cleaned *ex situ* (Matuszek, 2013). In COP therefore, the cleaned surfaces are visible and the effectiveness and endpoint of cleaning easily discernible, although certain degree of subjectivity cannot be excluded.

Some of the commercial disinfectants commonly used in food processing plants include peracetic acid-based compounds, quaternary ammonium compounds, aldehydes e.g. formaldehyde, peroxides e.g. hydrogen peroxide, alcohol-based e.g. ethanol, iodophors e.g. iodine, chlorine-based e.g. sodium hypochlorite, ozone and use of ultraviolet radiation (Korukluoglu *et al.*, 2006, Belessi *et al.*, 2011, Park *et al.*, 2015, Brown & Xu, 1999).

The choice of cleaning agents is often governed by various factors such as biocidal efficacy, type of soil involved, nature of surface to be cleaned, degree of hardness of water and environmental impact of the agents in terms of water and energy consumption, and waste water generated (Pascual *et al.*, 2007,Jurado-Alameda *et al.*, 2012, Spencer, 1972) among others.

2.6 GROWTH OF RESIDUAL MICROORGANISMS FROM CLEANING AND SANITIZING OF PROCESSING EQUIPMENT

Microorganisms have a tendency of growing and attaching themselves to surfaces with both organic and inorganic substances. Numerous operations are involved in the manufacture of products such as soft drinks and beverages and at each particular process/stage, there are cleaning and sanitation standards that have to be achieved during which there are residual microorganisms which form biofilm (Goode *et al.*, 2010). Biofilm is a convergence of microbial cells that are attached to a surface and enclosed in a film of extracellular polymers (Mortensen, 2014). Biofilms have been found in various surfaces and equipment in the food industry such as packaging machines, heat exchanger surfaces, mixers, floors and drains among others (Wirtanen, 2015). Development of biofilms is favored by insufficient cleaning of equipment and surfaces which is facilitated by low cleaning temperature, detergent concentration and cleaning time in addition to poor hygienic design (Mortensen, 2014).

Biofilm formation depends on such factors such as pH, temperature, bacteria strain, nutrients and surface attachment material (Akbas, 2015). Biofilm formation is complex occurring in steps involving initial attachment of the microorganisms to the surface through appendages such as pilli and flagella or through physical forces such as electrostatic interactions (Jamal *et al.,* 2017). This is followed by microbial cell multiplication leading to micro-colonies formation in which there is coordination of different types of microorganisms involving substrate exchange and production of metabolic products (Akbas, 2015).

Communication between cells then occurs forming the required cell density and this leads to an organized structure which is resistant to chemicals and disinfectants. Microbial cells continue to grow due to the presence of nutrients from the micro-colonies and also from the surrounding hydrophilic environment (Vasudevan, 2014). The final step involves the detachment of microbial cells from the biofilm to the surrounding area (Jamal *et al.,* 2017).

Environmental conditions around food processing areas contribute to the growth and development of residual microorganisms. The occurrence of microorganisms in raw materials, on food and contact surfaces, presence of water and nutrients from food or food debris are factors leading to the growth of residual microorganisms.

Various microorganisms have been shown to from biofilms in the soft drink and beverage industry. Pathogenic bacteria such as *Staphylococcus*, *Salmonella*, *Escherichia*, *Bacillus* and *Listeria* can adhere forming biofilms in glass, rubber, plastic and metal surfaces (Elhariry, 2008; Habimana *et al.,* 2010; Pan *et al.,* 2009). Some work has demonstrated the presence of *Bacillus* strains in various food environments (Shaheen *et al.,* 2010). *Listeria monocytogenes* has the ability to form biofilms in food industry on various surfaces resulting in food contamination. Some researchers have showed that *L. monocytogenes* has the ability to lodge itself on food processing equipment and surfaces and remain there for long periods (Gunduz & Tuncel, 2006; Keskinen *et al.,* 2008). *Escherichia coli* have also been shown to adhere to different surfaces through their flagella and membrane proteins forming biofilms (Houdt & Michiels, 2005).

There are various risks associated with the growth of residual microorganisms in processing equipment and surfaces such as microbial contamination of food industries leading to food safety issues such as food-borne diseases (Shia & Zhua, 2009). Biofilms can also decrease heat transfer rates during processing (Shia & Zhua, 2009), product contamination, blocking of product lines and corrosion of equipment (Mortensen, 2014).

2.7 MATERIALS USED IN THE FABRICATION OF FOOD PROCESSING EQUIPMENT

Equipment used in food processing have largely been designed based on safety, efficiency, quality of product and, sanitation requirements (Bilgili, 2006). Materials known to be used for food contact surfaces are metals and alloys such as stainless steel, rigid plastics such as teflon, rubber such as nitrile butyl and rubber polyurethane , glass, ceramic and in the developing countries, wood is also used (Srey *et al.,* 2013).

In the use of metals and alloys, emphasis is placed on the corrosion resistance of the material more so to salt and chlorine compounds (Moerman & Kastelein, 2013). American Iron and Steel Institute (AISI) types 304 and 316 stainless steel grades are commonly used due to their high corrosion resistance and physicochemical stability (Silva *et al.,* 2010; Nikoleiski, 2015). Stainless steel is also generally preferred because of high strength, availability in a wide range of forms, ease of machining and fabrication, and relatively low cost (Schmidt *et al.*, 2012)

Plastics are the backbone of the food packaging industry (Ossberger, 2015). However, in food processing equipment, they are used where metal-to-metal contact requires to be prevented, in covers and product conveying pipes (Moerman & Kastelein, 2013) owing to their corrosion resistance. Depending on the molecular structure and the macroscopic nature of plastic, the concern with their use in food processing is the potential of monomers and additives such as phthalates migrating into food (Bošnir *et al.*, 2007).

Rubbers also known as elastomers, are commonly used in gaskets and seals, due to their elasticity, process ability, material properties and price (Ng *et al.*, 2014). The disadvantage however, is that they can be degraded by cleaning agents and products processed, and are susceptible to thermal and mechanical stress (Moerman & Kastelein, 2013). The resultant effects are potential loss of bacterial tightness, retention of soil and microorganisms and leakage of product as well as lubricants from the equipment. There is also a potential of some compounds inherent in the rubber to migrate into food where there is direct contact (Moerman & Partington, 2014).

Glass on the other hand is used in light and sight openings of processing equipment to facilitate inspection of product and equipment. However, it is not recommended because of the risks associated with the brittle nature of glass (Ramos *et al.*, 2015) . Alternatives such as Perspex or polycarbonate transparent are generally used as replacements to eliminate these risks (Andrady & Neal, 2009).

Ceramics are used where very sensitive products are produced, generally as a coating of other stable materials. They are resistant to lye and acids, which are commonly used for cleaning of equipment and have the ability to withstand high pressure. However, they are brittle and porous, with a major concern of migration of heavy metals such as cadmium and lead into the food (Moerman & Partington, 2014).

Wood is mainly used in transportation, handling and in instances where it is beneficial for example barrels in the wines and spirits industry, wooden shelves in ripening of cheese and vinegar making among others. Usage of wood is discriminated against because of the risk of splinters and it is highly porous and absorbent, hence has a potential to harbor organic material and microorganisms (Fink *et al.,* 2013).

2.7.1 EQUIPMENT DESIGN AND FABRICATION IN THE DEVELOPING COUNTRIES

Equipment design and fabrication in the developing countries is not as elaborate as it is in the developed countries. This is more so for equipment for processing among the Micro, Small and Medium Enterprises (MSMEs).

The large food processing industries are part of the multinationals who import the equipment for processing from the mother countries of the multinational. The MSMEs do not work with specialized equipment. They utilize small-scale equipment such as blenders, cooking/pasteurization pans, and mixers, which are fabricated along the designs of the kitchen appliances. These equipment are operated as batch not as continuous and therefore the cleaning system is that of cleaning-out-of place (COP), which if done properly will be effective.

There are companies that have been set up to fabricate such equipment for a country like Kenya. These companies are observed to be fabricating the equipment from materials such as stainless steel and rigid plastic. An example of a company like that is the DK Industries based in Nairobi Kenya who import and fabricate all sorts of food processing equipment such as dough mixers, bread baking ovens, paste mixers, pasteurizers for milk and fruit juices and beverages, ketchup cookers, peanut butter mixers and fruit jam cookers. However, all these fabrications are miniaturized features of the European and American large-scale equipment with the simple exception that they are operated on a batch basis.

From our experience working with the microenterprises in Kenya, most of them operate from owners' domestic kitchens (1-5 employees) or in backyards of their residences, producing a diversity of products including potato crisps, various sauces, soft drinks and cakes, which are then channeled for sale in the markets including the supermarkets. The regulatory agency, Kenya Bureau of Standards, has a provision for certifying such level of enterprises and during inspection, appropriateness of the equipment is one of the aims as per the requirements of the Code of Practice for Hygiene in the Food and Drink Manufacturing Industry, East African Standard (EAS) 39: 2000. These enterprises utilize the domestic kitchen appliances for example fryers, cookers, ovens, mixing bowls, blenders and cooking pans, which in most cases form part of the utensils of domestic activities (Onyango *et al.,* 2014). There is a very active business at this level in the milling of grain to produce various meals and flours and their mixes, but this involves dry products and growth of microorganisms here is restricted to fungi.

At the small enterprise level, there may be a distinct separation of the enterprise and the kitchen, but the equipment is just a scale-up of the kitchen appliances. The design of the kitchen appliances is usually done in the developed countries of Europe and North America, though the fabrication may be done here by the parent companies or local agents. Either way, hygienic considerations were taken during the design of the appliances. At the Micro and Small enterprise level, the firm is completely removed from the kitchen and is often established in the part of the metropolis reserved for industry. The equipment are semi-industrial but complying with the designs of the large-scale equipment.

Generally, in the MSMEs, probably the main problem might not be so much the contamination of the product from the processing equipment, but from the poor sanitation and hygiene of the processing environment including the personnel. In Kenya, it has been observed that a number of the enterprises in this category use locally fabricated or improvised equipment with limited or no considerations of the hygienic design. There is also little knowledge by the entrepreneurs of the existing hygienic design requirements as well as the recommended elaborate cleaning and disinfection regimes.

2.8 INTERNATIONAL GUIDELINES IN THE DESIGN AND SELECTION OF THE FOOD PROCESSING EQUIPMENT

The criteria for hygienic design of food processing equipment is well outlined (Withers, 1996). Equipment design and construction standards such as the 3-A sanitary standards (Schmidt, 2012) and European Hygienic Design Engineering Group (EHEDG) guidelines provide the requirements and accepted practices for the hygienic design of food processing equipment, including specifications on surface finish and smoothness (Goff, 2007, Schmidt, 2012).

In Europe, food processing equipment must meet the hygiene and design requirements stipulated in the European Council Directive 98/37EC on Machinery (Bénézech *et al.*,2002). Regulation 852/2004 prescribes specific rules on the equipment relating to materials, construction, installation and maintenance (Velde & Meulen, 2011). On the other hand, in the

United States, requirements for the design, construction, and use of food processing equipment and utensils is stipulated in the Current Good Manufacturing Practices (CGMPs) regulations which are enforced by the Food and Drug Administration (FDA)(Fortin, 2011).

2.9 FABRICATION OF FOOD PROCESSING FOR THE SOFT DRINK AND BEVERAGE INDUSTRY FOR MSEs

Fabrication is defined as the process of constructing materials by combining several standardized parts (Piorkowski & McClements, 2013). Sanitary design is usually an important part of consideration in fabricating equipment for food processing applications. The main equipment in the soft drink industry include vessels, pasteurizers, tanks, coolers, blenders, filters, packaging and vending machines (Salas *et al.*, 2016). The main material used in the fabrication of equipment for the soft drink and beverage industry should be such that it does not form corrosion products that would contaminate the beverages.

In the soft drink and beverage plants, equipment such as tanks, heat exchangers and distillation columns are factory-built (Mamvura *et al.*, 2017). However, other equipment like fillers, holding tanks and small pipes are bought from manufacturers and joined on site. The holding tank is usually custom fabricated for optimal sanitation, and are constructed with stainless steel to prevent corrosion (Breyers & Ratner, 2004). The pipes and their interconnections are not accessible from the inside and this makes it difficult to control its welding. Joints that are inadequately fabricated can lead to compromise in the drink and beverage quality.

Poorly fabricated equipment and joints not well welded facilitate biofilm formation leading to microbial corrosion (Mamvura *et al.*, 2017). Low carbon content stainless steel is used for holding tanks and piping accessories that are fabricated with metal or welded sheet since they are resistant to the pH of drinks and beverages thus preventing corrosion. For equipment such as heat exchangers and coolers used for boiling liquids or for holding hot liquids, a more strongly passivating stainless steel is used (Mamvura *et al.,* 2017).

2.10 SOCIO-DEMOGRAPHIC FACTORS THAT INFLUENCE HYGIENE PRACTICE IN THE FOOD INDUSTRY

Food mishandling and poor hygiene practices in the food industry are some of the sources of food contamination leading to food-borne illnesses as they enable microbes to get into contact with food, food equipment and surfaces and in some cases multiplying and surviving to cause illnesses (Zain & Naing, 2002). The sanitation of the environment and personal hygiene are very key in the transmission of food-borne illnesses (Zain & Naing, 2002).

Hygiene practices in the food industry cover areas of handwashing, food handling, waste management, food storage conditions, use of sanitizers and disinfectants, regular medical checkup and use and change of hand gloves among others (Ifeadike *et al.,* 2014). Training and knowledge on food hygiene is one of the factors influencing hygiene practices in the food industry.

It is believed that training on food hygiene leads to an increase in knowledge on food hygiene consequently leading to improved hygienic practices even though this may not always give positive results. Rahman *et al.,* (2012) found that hygienic practices of food handlers with training on food safety increased compared to that of those without training. According to Galgamuwa *et al.,* (2016), lack of proper hygiene practices among food handlers was an indication of inadequate training on food hygiene practices.

A study conducted by Abdullahi *et al.,* (2016) showed that there was an association between sex and hygienic practices among workers in abattoirs. According to the study, male workers had better hygienic practices compared to the female workers. On the contrary, a study by Galgamuwa *et al.,* (2016) showed that women food handlers were more knowledgeable on food hygiene practices as compared to male handlers. A study in Sarawak showed that young food handlers had the best food hygiene practices (Rahman *et al.,* 2012). Byrd-Bredbenner *et al.,* (2007) reported similar results.

Lack of education makes one unaware of the risks associated with improper food handling. Poor hygiene practices in the food industry can be contributed to by poor levels of education (Prabhu, 2014). The level of education of food handlers in Sri Lanka was significantly correlated with their hygiene practices in handling of food (Galgamuwa *et al.,* 2016). Another study revealed that good hygiene practices were found among the highly educated food handlers (Prabhu, 2014).

2.11 CRITERIA FOR EVALUATION OF HYGIENE PRACTICE COMPLIANCE IN THE FOOD INDUSTRY

The criteria for evaluation for hygiene practice compliance in the drink manufacturing industry stipulates the requirements to ensure all aspects of hygiene are incorporated during production of soft drinks and beverages.

Personnel have the ability of causing food contamination since most microorganisms live on various parts of one's body such as nose, bowel, mouth and hair among others (KEBS, 2009). The criteria applied here to ensure good hygienic practices by personnel handling food or in contact with the production area involves appropriate training on hygiene practices by competent personnel and keeping records on the same; medical examination at regular intervals and ensuring that personnel suffering from any communicable disease do not come into contact with food (Codex Alimentarius, 1997). Ensuring that protective clothing is worn by every personnel entering the processing areas including visitors, separate footwear for use in the factory and the clothing maintained in clean conditions and not worn outside the factory. Personnel monitored to ensure that they do not bring jewellery in the production areas, provision of adequate toilet facilities, hand washing and sanitizing facilities (Codex Alimentarius, 1997).

Contamination of food can result from dirty equipment and unhygienic environment. Cleaning is therefore required to prevent food contamination. Cleaning as a criterion for evaluating hygienic practices involves ensuring that there is a documented procedure for cleaning all the equipment and surfaces in which food is processed including floors and windows, and a procedure to check the efficiency of cleaning through microbiological analysis of rinse water and swabbing of equipment and surfaces (Food Standards Agency, 2017). Ensuring that the plant, surfaces and equipment are cleaned at regular intervals prevents contamination of food. Pests are a big threat to food safety and proper sanitation, monitoring and raw material inspection is able to minimize or prevent pest infestation thereby limiting pesticide applications (Food Standards Agency, 2017). The criterion ensures that rodents, birds and other animals are excluded from the plant, food sources and refuses kept in pest-proof containers and well covered.

Storage, transport and distribution of products are so as to prevent contamination and deterioration of food products. Adequate storage facilities should be provided and kept under hygienic conditions with regular monitoring (KEBS, 2009). The vehicles used for distribution are easy to clean, free of odours and refrigerated where it is required. Conveyors for transporting food are cleaned and sanitized to avoid contamination. Cross contamination can occur between raw materials and the processed food products. Contamination can also happen from places such as microbiological laboratories, chemicals, boilers, effluent and detergents (Codex Alimentarius Agency, 1997). Checking to ensure that all areas are physically separated from each other within a factory to prevent cross contamination and access of personnel to different areas is critical (KEBS, 2009).

It is ensured that the food plant and equipment used in production are designed in order to safeguard the hygienic conditions. All the facilities are designed so as to enable thorough cleaning of all surfaces and substandard maintenance of facilities is considered noncompliance (Doménecha *et al.,* 2011). The plant is designed to eliminate all corners such that all areas are accessible for cleaning and inspection. Plant contact surfaces are designed to be smooth, non-toxic, non-absorbent and corrosion resistant, with no dead ends in pipes since they cannot be adequately cleaned (KEBS, 2009).

Another criterion is to ensure that the factory is located in such a place that is free from flooding, with clean air and free from odours. The ground is maintained and kept free from harborage of microorganisms and pests to prevent food contamination (Doménecha *et al.,* 2011). The roofs are maintained, clear of debris and bird droppings and walls free of cobwebs and mould. Floors are constructed with a water resistant material that is durable, resistant to cleaning agents and maintained in good conditions free form cracks and corrosion. Effective procedures are put in place for dealing with food safety hazards that may arise, to enable a recall of an implicated product (KEBS, 2009).

Ensuring that waste disposal systems are in place and that waste materials are collected and removed from the working areas in such a way that prevents contamination of products of the processing areas (Codex Alimentarius Agency, 1997). Records of all actions taken to assure the safety of the products are kept and all the relevant information that is required for maintaining hygiene. The records include: a record of all critical parameters and tests of finished products including microbiological results, records of adherence to cleaning programs, inspection of incoming materials, inspection of water storage facilities, screening of all the workers and their training on principles of hygiene (Food Standards Agency, 2017).

2.12 INFLUENCE OF EQUIPMENT DESIGN ON CLEANING, SANITIZATION AND POST-CLEANING MICROBIAL ACCUMULATIION

Unhygienic surface features retain residual food debris when food materials pass over, thereby encouraging growth of microorganisms harbored (Lelieveld & Holah, 2014b). These microorganisms such as bacteria, can adhere to and colonize food contact surfaces forming layered complex structures known as biofilms (Oulahal-Lagsir *et al.*, 2000), which gives them the ability to respond to and protect themselves against exposure to environmental stresses (Rajkovic *et al.*, 2010). According to Brooks & Flint (2008), the primary advantages of biofilm formation to the microorganisms include utilization of potential benefits of a community, defense against harmful conditions of antibiotics, detergents and sanitizers, and colonization of favorable niches.

Biofilms form in a series of specific steps (Pru, 2009). The initial step involves deposition of organic molecules from food on a surface and movement of microbial cells toward the surface, facilitated by flagella. This is followed by reversible attachment of the cells, irreversible adhesion, formation of micro colonies and finally synthesis of an extracellular sticky polymer which combines the individual micro colonies into one structure (Smirnov *et al.*, 2010, Shi & Zhu, 2009, Van Houdt *et al.*, 2004). Biofilms can develop on any material surface (Srey *et al.*, 2013), including glass, metal, rubber and plastic, and can form on most hydrated environments (Srivastava & Bhargava, 2016, Liaqat *et al.*,2009). There is no evidence that the nature of biofilms of food spoilage microorganisms and that of pathogenic microorganisms differ significantly (Lindsay & Flint, 2009). Both types of biofilms have the potential to contaminate food products directly from the processing equipment (Bagge *et al.*, 2001).

Microorganisms of concern in food processing plants include *Escherichia coli O157:H7, Campylobacter jejuni, Listeria monocytogenes, Pseudomonas spp., Salmonella spp., Staphylococcus spp.,* and *Bacillus cereus* (Cappitelli *et al.*, 2014), and which are known to form biofilms on food contact surfaces (Brooks *et al.*, 2008, Hüsmark *et al.*, 1999). Faults in equipment such as crevices, cracks, corners, dead ends, valves and gaskets are vulnerable avenues for biofilms accumulation (Todhanakasem, 2013). Such defects provide protective micro niches where these microorganisms survive cleaning and disinfection (Lindsay & Flint, 2009).

Although cleaning and disinfection procedures may be elaborate and implemented strictly, they may only be effective for removal of planktonic (free flowing) cells and newly formed, but not well developed biofilms (Orgaz *et al.*, 2011). Park *et al.*, (2015) established that a higher concentration of ethanol was needed to destroy attached microbial cells in biofilms, as compared to those growing as planktonic cells. Removal of microbial cells that are irreversibly attached as biofilms is difficult, requiring strong shear force by scrubbing and scrapping, and use of chemicals to break the attachment forces, or application of enzymes, detergents, sanitizers, surfactants or heat (Elhariry *et al.*, 2012).

Attachment of pathogenic microorganisms to food-contact surfaces increases the risk of food product contamination during processing (Van Houdt & Michiels, 2010). According to Shi & Zhu (2009) and Cunault *et al.,* (2015), results from various investigations indicate that biofilms containing pathogens are leading causes of food contamination in production facilities and subsequent transmission of diseases. Inadequate cleaning and disinfection of food contact surfaces therefore poses a risk of contamination of food products with both spoilage and pathogenic microorganisms (Moore & Griffith, 2002). Therefore, choice of material for direct food contact in equipment design is key, as this influences the effectiveness of cleaning and disinfection, and subsequent microbial cell attachment, and therefore impacts negatively on the hygiene of processing equipment (Van Houdt & Michiels, 2010).

2.13 IMPACT OF MICROBIAL CONTAMINATION OF FOOD DURING PROCESSING ON HUMAN HEALTH AND THE ECONOMY

WHO (2015) reports that unsafe foods are a health threat globally and endangers the vulnerable populations including infants, young children, the elderly, pregnant women and those with opportunistic underlying illnesses.

Biofilms pose a great challenge in the food and beverage industry as they cause spoilage leading to huge losses and significant costs in control strategies (Lindsay & Flint, 2009). The biofilms are known to cause various infectious diseases to humans (Srivastava & Bhargava, 2016) and are very difficult to control in the medical and industrial fields due to high resistance to antibiotics and disinfectants (Liaqat *et al.*, 2009). The resistance is attributed to the mechanical protection offered by formation of the Extracellular Polymeric Substance (EPS), which contain exopolysaccharides, protein and nucleic acid (Belessi *et al.,* 2011). According to Yang *et al.*, (2011), infections by biofilms may be as a result of interaction of several pathogenic bacteria and not colonization by one bacterium. Microbial fouling also causes deposits on equipment surfaces which can be obviated by frequent and expensive cleaning for efficient and overall plant sterility (Fryer, 1989).

Food safety failures which result in product recalls leads to companies incurring significant costs, up to millions of dollars in the recall procedures, reprocessing and disposal of contaminated food (Leonard *et al.,* 2003, Henson & Hooker, 2001). Firms and even individual consumers may also face product liability costs in the event of actual food-borne illnesses or injuries occurring as a result of consumption of contaminated food (Haymerle, 2011; Robert *et al.,* 2004). Resultant negative publicity may lead to reduction of consumer demand for products hence loss of brand capital, subsequent loss of market share (Xie *et al.,* 2009,) and eventual bankruptcy of the company. On the other hand, import bans on such products imposed by other nations result in huge economic losses to the affected manufacturing sector and to the exporting country as a whole (Boisvert *et al.,* 2012).

CHAPTER THREE: STUDY DESIGN AND METHODOLOGY

3.1 STUDY DESIGN

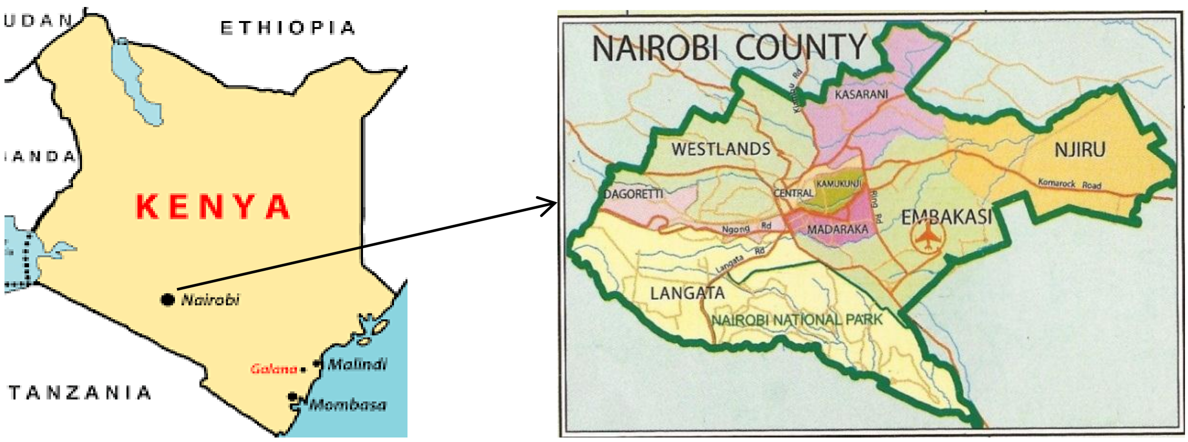
This was a cross sectional study design with an analytical component and was carried out between February and July 2017.

3.2 METHODOLOGY

3.2.1 Study Site

The study was carried out in Nairobi County and the neighbouring parts of Machakos, Kajiado and Kiambu Counties. The area was selected based on the geographical coverage of Kenya Bureau of Standards (KEBS) Nairobi office.

Nairobi is Kenya's capital and is the largest city in East Africa, with the population enumerated at 3.138 Million in the 2009 census and has an estimated 4% annual population growth rate (KNBS, 2015). The city covers an area of 696 km² and borders Kiambu, Kajiado and Machakos counties to the North, South and South East respectively. Figure 3.1 A and B shows a map of Kenya and Nairobi County respectively.



A B

Figure 3.1: Study site - Map of Kenya (A) and Nairobi County (B). Source: Google maps (2018)

3.2.2 Population

The population included all the Micro and Small enterprises existing in the study area dealing in soft drinks.

3.2.3 Sampling Frame

These included all the Micro and Small enterprises in the soft drink industry registered by the Registrar of Companies and by Kenya Bureau of Standards (KEBS) under the Product Certification Scheme (Standardization Mark scheme). There were a total of 78 enterprises registered under this category as at December 2016.

3.2.4 Sample Size Determination

Out of the population of 78 enterprises, only 26 were active and hence targeted for the study. Out of these, 18 enterprises agreed to participate and they were all taken as the sample.

3.2.5 Sampling Procedure

Purposive sampling was used to select Nairobi county and its environs as a study area. Stratified and randomised sampling procedures were then employed to select the enterprises, covering the Micro and Small companies in the soft drink processing industry. Enterprises in these locations mainly supply their products to the populace living in Nairobi. The enterprises were selected based on the number of employees and annual turnover, according to the definition of the Micro and Small Enterprises Act number 55 of 2012 (GoK, 2012).

There are a total of 26 active soft drink processing enterprises in this category, which are registered by KEBS. A total of 18 enterprises agreed to participate and they were therefore taken as exhaustive sample and coded as C1 to C18 for confidentiality.

3.2.6 Data Collection Tools

The data was collected using a pretested checklist and a semi-structured questionnaire as study tools. The checklist contained the seven key aspects of hygienic design and construction, covering a total of fourteen requirements of the European Hygienic Equipment Design Group (EHEDG) Criteria of 2004. It covered aspects on surfaces and geometry, surface finish/surface roughness, drainability and layout, installation, welding, supports for piping and equipment and quality of insulation.

The questionnaire on the other hand focused on the type of equipment used for processing, considerations for selection of the equipment, existence of a maintenance programme, constraints encountered during purchase, the hygienic practices including the cleaning regimes, cleaning process, detergents/sanitizers used, source of water, regularity of cleaning, verification activities, cleaning records maintenance, constraints encountered during cleaning and regulatory authorities involved in the enforcement of regulations in the sector.

3.2.7 Data collection Procedures

3.2.7.1 Administration of questionnaire and use of checklist

Each enterprise was visited and the questionnaire administered to the personnel in charge of production and quality control in the selected enterprises through one on one interviews. Observations and physical inspection of the sampled equipment was applied in filling of the checklist to assess the compliance with the European Hygienic Engineering and Design Group (EHEDG). According to ~~(~~Nikoleiski (2015), hygienic design reviews are easily and effectively carried out using checklists based on specified design principles with questions being answered as “yes” or “no” depending on compliance or non-compliance to the criteria.

3.2.7.2 Microbiological Swabbing

Microbial swabbing was carried out on food contact surfaces using horizontal methods according to ISO 18593: 2004 (Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs), using sterile rayon tipped swabs pre-moistened in Tryptose Soya Broth (TSB) and steel templates. The sampling locations for the 17 enterprises were selected based on "criticality indexes" 1, 2 and 3 with a modification on the frequency *(One enterprise out of the total 18 opted out of the research)*. Sampling was done once in each enterprise as described by Jacxsens *et al.*, (2009) since the objective of the study was to provide an overall Surface Microbial Load (SML) of the processing equipment, based on compliance to the hygienic design criteria and effectiveness of the cleaning and sanitizing procedures.

The criticality indexes scheme is used for establishing an environmental monitoring programme and determining the monitoring frequency. The programme involves assessment of risk on potential impact of contamination of the surface (Table 3.1) and is focussed on targeting critical steps in the manufacturing process. Higher weighting is given to dirtier activities, areas where dirty activities are performed in close relative proximity to clean areas, areas which are often wet, areas with open drains and areas with high levels of staff activity.

Table 3.1: Recommended post-processing environmental monitoring frequency for food production facilities by Microgen Bioproducts Ltd., Camberley, United Kingdom (UK)).

Criticality Index	Likelihood of Impact on Finished Product	Definition of Sites	*Monitoring Frequency
1	Highly Likely	Mixing and Filling machines, work places	Daily or Each Batch
2	Likely	Packaging areas or areas in which final handling is performed	Weekly
3	Moderately likely	Areas where processed food is exposed to the environment	Fortnightly
4	Unlikely	Cold areas where little or no processing is performed	Monthly
5	Very unlikely	Areas in which indirect exposure to prepared and packaged product is unlikely	Three Monthly
6	Highly unlikely	Any are that is uncontrolled or where microbial contamination is very unlikely such as freezers.	Six Monthly

Different critical spots were sampled from the food contact surfaces depending on the type of equipment in use, after routine cleaning and disinfection in each of the 17 enterprises. Surfaces cleaned after each use are usually assessed for effectiveness after each cleaning regime and prior to reuse, to give an almost accurate reflection of the potential of cross-contamination to the food products by measuring residual microorganisms still present on the surface after cleaning (Tebbutt *et al.*, 2007) (Hofmann & Rugh, 2014). The sampling locations were selected based on "criticality indexes" environmental monitoring programme from Microgen Bioproducts (Microgen Bioproducts Ltd., Camberly, UK) and therefore targeted the critical steps in the manufacturing process, including the final product and sites which may serve as harbours of resident organisms. A standard $10cm^2$ area was sampled using sterile steel templates for regular (flat) surfaces and for irregular (non-flat) surfaces, approximately half the surface was sampled as described by Tebbutt *et al.,* (2007). Sterile rayon tipped swabs pre-moistened in Tryptose Soya Broth (TSB) to increase sensitivity of the test were used. The swabs were rotated while being drawn on the surface in one direction while applying maximum pressure on the swab, repeated in the opposite direction, and broken off into a universal bottle containing the TSB, which was also used as the transport media (Van Houdt *et al.,* 2004). According to Verran *et al.,* (2002), there are various methods for microbiological determination of surface contamination. However, the most common used method is the total viable count with involves removal of contaminating microorganisms from surfaces, culturing and enumeration of resultant colonies.

Hands of personnel working at the filling/packaging point or those that were in direct contact with the finished product were also swabbed to give an indication of personnel hygiene practices. The swab samples were transported in cooler boxes at 4^{O}C, held under similar refrigeration temperatures and analysed within 24 hours.

A total of 109 samples were drawn for analysis which comprised of 30 hand swabs of food handlers, 67 food contact surfaces and 12 end products.

3.2.6 Analytical Methods

3.2.6.1 Quality Control, Isolation of Microorganisms and Confirmatory Tests

The sterility of the rayon tipped swabs was confirmed using Tryptone Soya Agar (non-selective media) by streaking both pre-moistened and dry swabs separately in the media and incubating at 37^{O}C for 24 hours.

Petridishes were cleaned and oven sterilized at 170^{O}C for 2 hours. All working surfaces, hands and pipettes were continuously sterilized using 70% alcohol as described by Lahou & Uyttendaele, (2014). Pipette tips were cleaned by soaking in acetone for 12-24 hours, rinsed with warm water, dried in a prior clave and autoclaved at sterilization temperature/time combination of 121^{O}C for 15 minutes. The growth media were prepared and sterilized in an autoclave for 121^{O}C for 15 minutes (Lahou & Uyttendaele, 2014). Inoculation of samples in growth media was carried out in a lamina flow hood to ensure a sterile working environment. Sterile conditions were maintained within the laboratory by use of air pressure differentials, ensuring that doors and windows remained closed and use of air conditioning, which was checked for cleaning and maintenance on a monthly basis.

Pure cultures of the respective microorganisms were inoculated in the specific growth media and incubated as positive controls and blank media as negative controls for the parameters analysed for all samples of swabs.

The swab samples were analysed for selected microorganisms using standardized analytical methods based on International Organization for Standardization (ISO) standards as shown in (Table 3.2).

Table 3.2: Microbiological parameters selected and analytical test methods

Microorganism	**Analytical test method**
Escherichia coli	ISO 7521: 2005
Staphyloccocus aureus	KS ISO 6888-1: 1999
Pseudomonas aeruginosa	KS 16266: 2006
Listeria monocytogenes	ISO 11290-2: 1998
Coliforms	ISO 4832: 2006
Enterobacteriaceae	ISO 21528-2: 2004
Total Viable Count (TVC)	ISO 4833: 2003

Detection and enumeration of the microorganisms was carried out using specific selective growth media (Oxoid Ltd, UK) and the recommended confirmation methods for presumptive positive tests carried out in accordance with methods prescribed in the ISO standards. Serial dilutions were performed where applicable for enumeration purposes and pre-enrichment and confirmatory tests performed where detection was required. The experiments were carried out in triplicate and results were expressed in terms of means of the coliform forming units per square centimeter (cfu/cm^2). The colonies were counted both manually and using an automated colony counter.

Analysis of samples was carried out at the Kenya Bureau of Standards (KEBS) microbiological laboratory which is accredited to ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories, by South African National Accreditation Service (SANAS).

3.2.7 Data Analysis

Objective 1: The characteristics of Micro and Small Enterprises and diversity of the products produced was evaluated. The data obtained was presented in tabular form.

Objective 2: The qualitative data obtained was analysed using SPSS version 20 (SPSS Inc.) and Microsoft Office Excel 2010. The data was coded C, N and NA, where C denotes “complying”, N “not complying” and NA “not applicable”. The analysed data was presented in form of frequency tables and graphs.

Objective 3: The data obtained was analysed using SPSS version 20 (SPSS Inc.) and Microsoft Office Excel 2010. The qualitative data was given numerical codes for purposes of analysis and the analysed data presented in form of frequency tables and graphs using.

Objective 4: The data obtained was analysed using SPSS version 20 (SPSS Inc.) and Microsoft Office Excel 2010 and presented in form of frequency tables and graphs using.

CHAPTER FOUR: RESULTS AND DISCUSSIONS

The results of the study including discussions are presented in this chapter in terms and the order of the specific objectives. The results are presented as narratives, in figures and tables.

4.1 DIVERSITY AND CHARACTERISTICS OF THE ENTERPRISES

The results discussed here represent study objective number 1.

4.1.1 Diversity of Products and Category of Enterprises

The diversity of the enterprises in terms of product diversification and categorization was as shown in Tables 4.1 and 4.2.

All the 18 enterprises studied fall under the Micro and Small Enterprises category according to the Micro and Small Enterprises Act of 2012, with a work force of 5 to 50 employees and annual turnover of between KES 200,000 and 5 Million. The investment or registered capital of the enterprises was not assessed, since none of the enterprises had valued their assets to establish the investment or capital. The enterprises are all registered under the Registrar of Companies and with Kenya Bureau of Standards Product Certification Scheme (Standardization Mark Scheme). The enterprises process soft drinks which include fruit flavoured drinks including that in powdered form, fruit based soft drinks (minimum of 10% fruit ingredients), cordials and carbonated drinks. The product categorization is based on the definition of the Kenya and East Africa standards for the individual products. The daily production capacity of the active enterprises ranges between 10 and 8000 litres.

Majority of the enterprises (50%) were categorized as small based on their number of employees and annual turnover, while 39% were categorized as micro (GoK, 2012). Two out of the eighteen (11%) enterprises were categorized under "others" since either the turnover or number of employees was within the different categories. C14 had between 10 and 50 employees but with an annual turnover of less than five hundred thousand shilling. C13 on the other hand had less than 10 employees but with an annual turnover of between five hundred thousand and five million shillings (Table 4.1).

Table 4.1: Category of Enterprises based on Number of Employees and Annual Turnover

Category	Frequency of Enterprises	Percentage of Enterprises (%)
Small	9	50
Micro	7	39
Others	2	11

Up to 44% of the respondents process fruit flavoured drinks, 33% fruit based soft drinks, 6%, one enterprise, produces carbonated drinks in addition to fruit based soft drinks and 6% (C14) produces powdered fruit flavoured drinks. Another 6% (C8) processes fresh unpasteurized juices which are preserved exclusively by freezing and chilling, while 11% (C11 and C13) processes pasteurized fruit juices for bottling (Figure 4.2).

Table 4.2: Diversity of Products

Product	Frequency of Enterprises	Percentage of Enterprises (%)
Fruit-flavoured drinks	8	44
Fruit-based soft drinks	6	33
Carbonated drinks	1	6
Fruit-flavoured drink in powder (solid) form	1	6
Pasteurized juices	2	11
Fresh juices (non-pasteurized)	1	6
Cordials	1	6

The daily production capacity was based on average production, with most of the enterprises indicating that production was not regular since it was driven by demand, which was affected by various factors including weather conditions (mostly consumed during hot periods) (EAC, 2000). Interestingly, C13 had higher average annual turnover with less employees and less production capacity per day as compared to the other enterprises. This could be attributed to the fact that production was consistent as a result of stability of the market.

4.1.2 Level of Education (Technical Competence) of Respondents

The highest academic qualification for majority of production staff of the respondents (44%) was degree, out of which four i.e. C2, C4, C13 and C16 had food related backgrounds i.e. Bachelor of Science in Food Science and Technology while C14 procured the services of a part time consultant with the same training. Three of the enterprises, C5, C10 and C12 had Bachelor of Technology, Bachelor of Business Administration and Bachelor of Arts in Human Resource degrees respectively. The respondents who had Diploma as the highest qualification were 28%, with three of them (C1, C9 and C11) in Food Science while two (C15 and C17) in non-food related background i.e. Diploma in Information Technology and Tours and Travels respectively. The highest qualification for 17%) of respondents (C3, C6 and C18) was O-levels certificate, PhD in Environmental Science for 6% (C8) and Certificate in Foods and Beverages for another 6% (C7).

Therefore, only half (50%) of the respondents had personnel who were technically competent with backgrounds in food related training to oversee production in a food processing enterprise as shown in Table 4.3. This has an implication on the selection of processing equipment that complies with the hygienic design requirements.

Table 4.3: Highest academic qualification of the personnel by enterprises

Highest Qualification	Number of MSEs	Distribution (Percentage)
Doctorate	1	6
Masters degree	0	0
Bachelors degree	8	44
Diploma	5	28
Certificate	1	6
Secondary Level	3	17

4.1.3 Inspection by Regulatory Agency

The main National authorities carrying out regulatory activities in the enterprises are Kenya Bureau of Standards (KEBS), Public Health Department of the respective County Governments and National Environment Management Authority (NEMA). Others are County Government Fire Department, Kenya Industrial Property Institute (KIPI), Kenya Revenue Authority (KRA) and the National Police Service (NPS) of Kenya.

All the 18 enterprises indicated that KEBS carries out inspections at their premises for compliance with Good Manufacturing Practices (GMP) and general hygiene conditions throughout the production process and sampled products for analysis. The products are tested against the requirements of the relevant standards for purposes of product certification, which facilitates access to the market. The visits by KEBS are annual unless the products fails to comply with the requirements of the applicable standards, in which case more visits are made. All the 18 confirmed that they got feedback on the results of analysis.

Majority of the respondents (83%) are visited by Public Health Department of the County Government for inspection of compliance of the premises to hygiene conditions and confirmation of validity of food handlers' certificates of medical examination while 17% had never been visited by the regulator (Figure 4.1). Out of those visited, 47% (n=7) indicated that they are inspected every 6 months, 20% (n=3) every 3 months, 27% (n=4) experienced random adhoc visits while 6% (n=1) is visited annually for inspection (Figure 4.2).

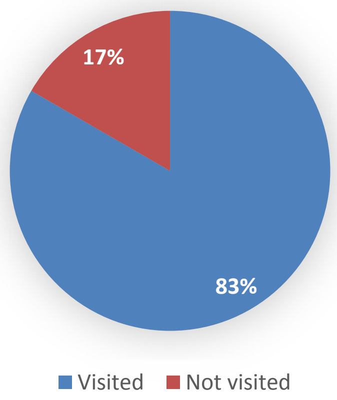


Figure 4.1: Visits of enterprises by the Public Health Department

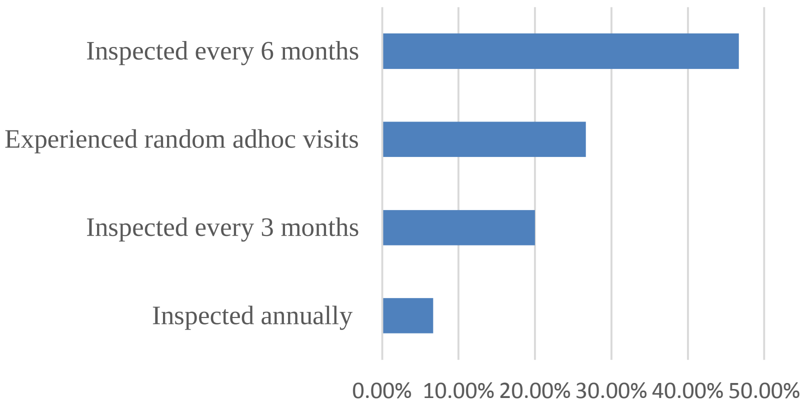


Figure 4.2: Frequency of visits of enterprises by the Public Health Department of the County

Half of the respondents, (50%) are regulated by NEMA, mainly on waste management practices (Figure 4.3). Out of those regulated by NEMA, 11% are visited quarterly for inspection of the boiler in addition to waste disposal, 56% are inspected annually, 11% once every two years and another 11% indicated they were rarely visited. One respondent indicated that a one off Environmental Impact Assessment (EIA) was carried out before and after set up of the plant with no subsequent visits since then (Figure 4.4).

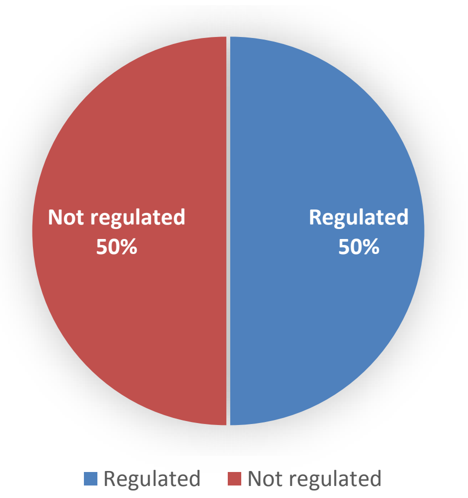


Figure 4.3: NEMA Regulation of enterprises

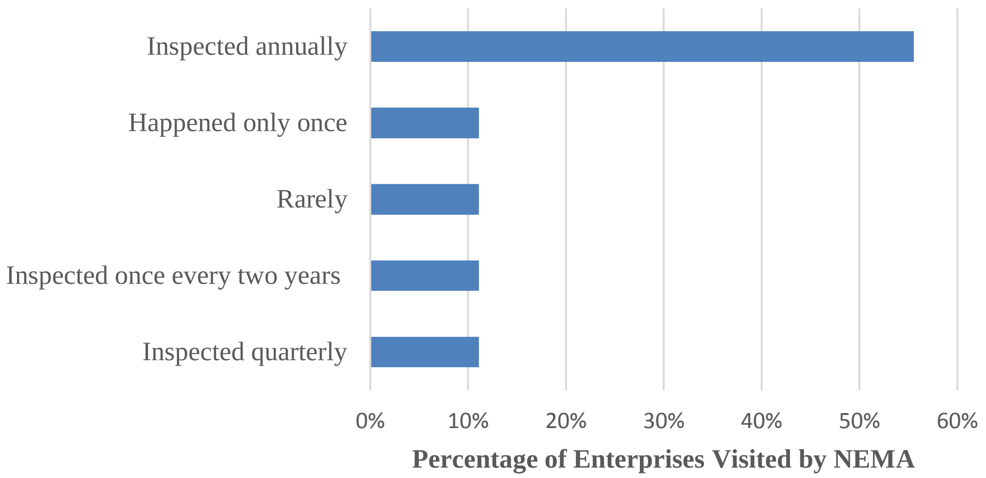


Figure 4.4: Frequency of Inspections of enterprises by NEMA

Other bodies who regulate the sector are KIPI for authenticity of brand names as indicated by 6% of the enterprises, Ministry of Labour for assessment of staff productivity and in house training 6%, Kenya police visited 6% with no specified role, County Government Fire

Department for inspection for issuance of fire clearance certificate 6% and 6% cited regulation by KRA for tax compliance audits.

None of the enterprises are regulated for compliance of processing equipment to hygienic design criteria. This is reflected in the findings of the study which show that most of the hygienic design requirements as per the EHEDG criteria were not complied with by the 18 enterprises, as compared to those that were complied with. It is evident from the findings that the food control regulatory framework has duplication of roles and overlaps as in the case of KEBS and Public Health Department, who both carry out hygiene inspection and draw samples for analysis. The regulation by the other authorities was not uniformly applied across the 18 sampled enterprises, including the regularity of visits.

4.2 PROCESSING EQUIPMENT CHARACTERISTICS AND COMPLIANCE WITH HYGIENIC DESIGN CONSIDERATIONS

The results discussed here represent study objective number 2.

4.2.1 Type and Source of Processing Equipment Used

A total of 65 equipment which varied in type and brands were sampled from the 18 enterprises under study (Table 4.4). The findings of the study show that Micro and Small enterprises in the soft drink and beverage industry used various equipment including mixing and holding tanks which represented 6% of the total equipment, batch pasteurizers (8%), sachet filling machines (3%), stainless steel pumps (3%) and water filtration units (12%).

The specialized equipment were batch pasteurizers, continuous line pasteurizers (3%), homogenizers (2%) and filling machines for pouches (2%), cup or bottle (5%). However, the rest were assorted improvised equipment such as plastic buckets, jugs and wooden mixing sticks which represented the majority of the total equipment used (18%) among the enterprises.

Table 4.4: Type and Source of Processing Equipment Used

Equipment Category	Frequency	Percentage (%)	Source
Assorted improvised (Plastic buckets/drums, jugs, wooden stirrers, aluminium/stainless steel sufurias)	12	18	Kenya
Batch pasteurizer	5	8	Kenya, Germany, China
Blender	1	2	Italy
Chiller	1	2	Italy
Continuous Line Pasteurizer	2	3	Germany
Cup filling machine	1	2	China
Fiber tub (washing trough)	1	2	Kenya
Filling line	3	5	Kenya, India, Germany
Filling tank	2	3	Kenya
Ginger crusher	1	2	Kenya
Hard plastic sinks	1	2	Kenya
Holding tanks	2	3	Kenya, China
Homogenizer	1	2	China
Mango slicer	1	2	Italy
Mixing and holding tanks	4	6	Kenya, China, Taiwan, Germany
Numerical Control Liquid filling machine	1	2	China
Pineapple slicer	1	2	Germany
Plastic mixing/holding tanks	2	3	Kenya
plastic pipes	1	2	Kenya
Plastic raw water tanks	2	3	Kenya
Pulper	2	3	Kenya
Stainles steel pump	2	3	Italy
Satchet filling machine (line)	2	3	China
Semi-automatic filmatic packaging machine	1	2	South Africa
Stainless steel mixing tank	3	5	Kenya
Stainless steel tables	1	2	Kenya
Sugar cane juice extractor	1	2	India
Water filtration system	8	12	China, Kenya, Italy, UK

In terms of source, majority of the equipment (58%) were locally fabricated in Kenya and 17% imported from China. Others were sourced from Italy (8%), Germany (8%), India (5%), UK (2%), South Africa (2%) and Taiwan (2%) as shown in Figure 4.5. Some of the equipment were purchased from local supermarkets or dealers of equipment, with no supply of information on the country of origin or brand from the traders. Out of the locally sourced equipment, the common suppliers included Davis & Shirtliff for water filtration systems and pumps, Kenya Industrial Research and Development Institute (KIRDI) and local fabricators mainly based in Kayole and Kariobangi areas located within Nairobi, among others.

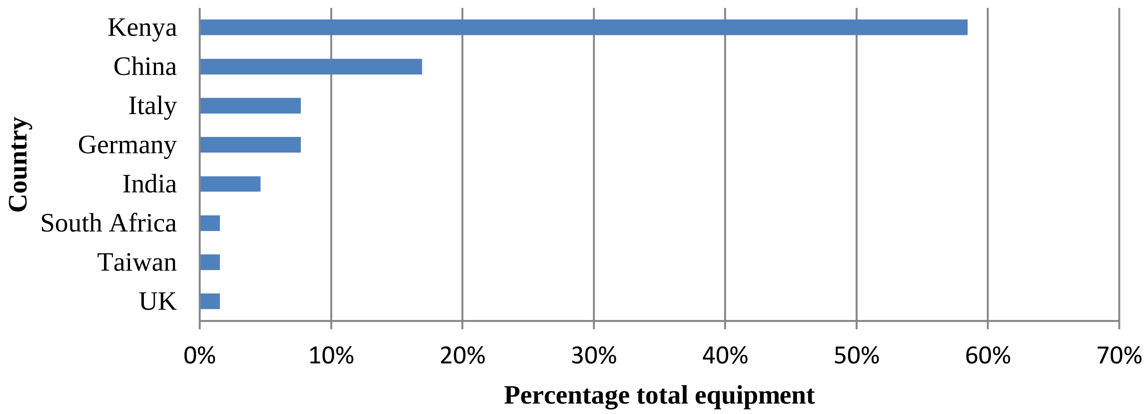


Figure 4.5: Source of Processing Equipment by Country

4.2.2 Considerations for Selection of Equipment

The enterprises considered various factors in the selection of the processing equipment as shown in Figure 4.6. Majority of the enterprises studied (94%) stated that cost was the major consideration for selection of the processing equipment. This is reflected in the sourcing of equipment which shows that majority were sourced locally within Kenya (locally fabricated hence affordable) followed by China, which is deemed a cheap source. This is probably also attributable to the difficulty faced by Micro and Small enterprises in accessing financial credit or funding, owing to shortcomings such as lack of sufficient documentation to support loan applications and lack of security among others, as reported by Omar & T. Anas (2014) and Simbulan (2017). Slightly more than half (56%) stated advice by a technical person, which includes the seller in some instances, as a consideration for purchase of equipment. Only 6% of the enterprises indicated they were advised by a friend/acquaintance while 17% additionally considered ease of use and ease of cleaning of the equipment. Other factors considered were processing capacity, availability of spare parts locally, flexibility of use in processing other products and size of equipment in relation to space constraints within the processing facility.

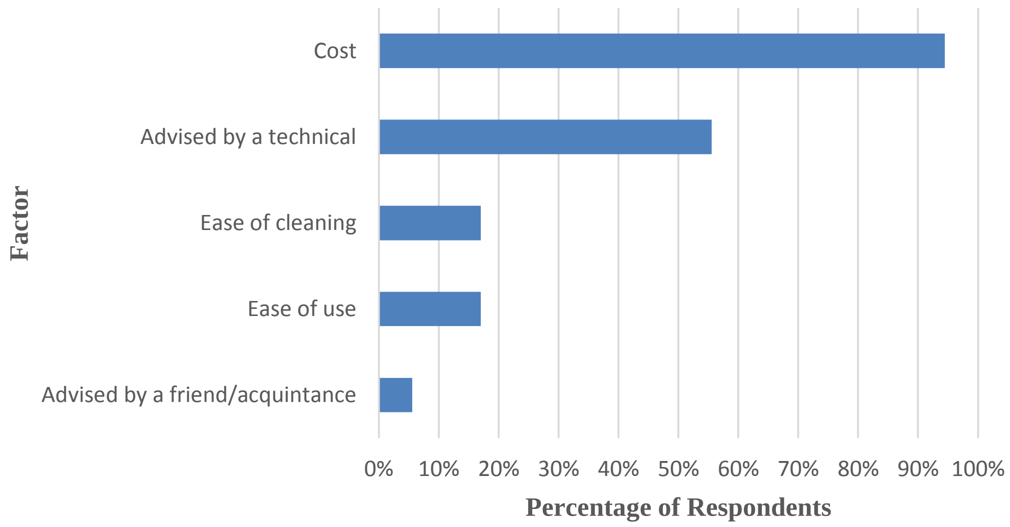


Figure 4.6: Considerations for Selection of Equipment

4.2.3 Awareness of Hygienic Design Criteria

Only 11% of the enterprises were aware of the existence of requirements of hygienic design of food processing equipment. However, this was purely based on experience of the Quality Assurance Manager (QAM) from working with other food processors and general knowledge but not specifically on existence of documented criteria on the same. The majority of respondents, 89%, had no knowledge of the existing criteria or what the hygienic design criteria entailed. Out of these, 35% were only aware that equipment used in the food processing industry should be made of stainless steel, with no specifics on the different grades recommended. This is partly attributed to the fact that only half (50%) of the respondents had technical backgrounds with trainings in food related courses. Lack of awareness of the hygienic design requirements by both the equipment fabricators and processors is one of the main determining factors of compliance of the processing equipment used to the hygienic design criteria.

The European Union Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended for food contact requires that business operators take account of the adequacy of personnel, their knowledge and skills as is necessary, to ensure that finished materials and articles comply with applicable rules (Moerman & Partington, 2014). This implies that technical know-how is critical in food safety.

4.2.4 Purchasing Constraints

While most (61%) stated no challenges in the purchasing process, a few of the enterprises 39% cited challenges such as in the selection of equipment from different available designs and models, dishonesty amongst middle men and sellers in terms of pricing and quality of material used for instance stainless steel, getting specifications met and failure to meet agreed upon timelines for fabrication and delivery by suppliers.

4.2.5 Maintenance Programmes

Majority of the companies (78%), have some kind of maintenance programme in place for the equipment, while 22% indicated they had none. The programmes were generally basic across the enterprises, involving servicing of machinery parts (lubrication, re-adjustments and replacement of worn out parts), changing of filters for water filtration units and dismantling to facilitate cleaning for inaccessible equipment such as pumps. This means that the equipment used by some of the MSEs are not well maintained, therefore implying that the full efficiency is not utilized. Additionally, lack of maintenance or servicing may lead to food safety risks like having physical hazards such as loose bolts and nuts contaminating the product. Equipment should also be designed, constructed, fabricated and maintained to prevent the ingress, survival and multiplication of microorganisms. Matuszek (2013) asserts that maintenance service should be adequate to the food system and items of equipment critical to food safety should be carefully inspected and serviced, to eliminate potential causes of product contamination.

4.2.6 Compliance with the Hygienic Design Criteria

Out of the fourteen requirements of the EHEDG criteria, only two had the highest percentage of the enterprises complying in total at 94.44% and 72.22% as compared to the twelve requirements that were not complied with (Table 4.5). The requirements were on sealing of equipment and support structures to supporting surfaces with elimination of gaps and pockets and adequate clearance between equipment and civil construction. These requirements were easily complied with since most of them were placed on top of surfaces such as tables or supported with metal framed structures.

One of the fourteen requirements which focused on product not in contact with screw threads had 50% of the enterprises complying and 50% not complying. Some of those complying with product not in contact with screw thread was because they used improvised equipment such as buckets and pans which do not have pipe connections. The ventilation in all the enterprises was adequate and therefore prevented excessive build-up of vapours and steam condensation.

The least complied with requirements were product contact surfaces being free of imperfections such as crevices, type of food contact surface e.g. stainless steel, avoidance of horizontal surfaces (surfaces slope to one side) and welded joints free of imperfections, where 88.89%, 77.78%, 77.77% and 66.67% of the enterprises respectively were not compliant as shown in Table 4.5.

Table 4.5: Level of Compliance with the European Hygienic Engineering and Design Group (EHEDG) Criteria

*Clause of EHEDG Criteria	Hygienic Design Requirement	**% Level of Compliance		
		C	N	NA
6.2.1	Equipment and pipe connections are aligned	33.33	44.45	22.22
6.2.2	Product is not in contact with screw threads.	50.00	50.00	0.00
6.2.3	All surfaces in contact with the product are easily accessible for visual inspection and manual cleaning.	38.89	61.12	0.00
6.3.1	Product surfaces are free of imperfections such as crevices, pits, folds and surface ruptures.	11.11	88.89	0.00
6.3.2	Type of food contact surface e.g. steel	22.22	77.78	0.00
6.4.1	The exterior and interior parts of equipment are self-draining	22.22	72.22	5.56
6.4.2	Surfaces slope to one side i.e. horizontal surfaces are avoided	22.22	77.77	0.00
6.5.1	The risk of condensation on equipment, pipework and internal surfaces of the building are avoided	44.44	16.67	38.89
6.5.2	Condensate diverts away from the product (where the above is unavoidable).	38.89	16.67	44.44
6.5.3	Equipment and support structures are sealed to the supporting surface (floors, walls, columns, ceiling) in such a way that no pockets or gaps exist.	94.44	5.56	0.00
6.5.4	Any clearance between equipment and civil construction (floors, walls and ceiling) is adequate for cleaning and inspection.	72.22	27.78	0.00
6.6	Permanent metal to metal product contact joints are continuously welded and free of imperfections.	11.11	66.67	22.22
6.7	Supports for piping or equipment are fabricated and installed such that no water or soils can remain on the surface within the supports.	44.44	50.00	5.56
6.8	Insulation materials are clad with stainless steel, which is fully welded such that no ingress of air or moisture is possible.	5.56	11.12	83.33

***The numbering of the clauses was modified for purposes of separating the specific requirements.**

***The percentages represent the level of compliance of the enterprises to the EHEDG criteria* where *"C" denotes* Complying, *N" not complying and "NA" not applicable*

"Complying" meant that all the equipment sampled in the enterprises were compliant with the EHEDG criteria and *"Not complying"* meant all or some of the equipment sampled in the enterprises were not compliant with the requirements. *"Not applicable"* meant the specific

aspect did not apply to the equipment. For example for insulation and welding, NA meant no insulation was necessary and no welding was necessary on equipment.

The finishing of welding on the equipment joints of those not complying with the requirement on welded joints was rough. This may be attributed to the fact that most of the equipment sampled were locally fabricated by “jua kali” artisans who are not very quality conscious and have no technical knowledge on the hygienic design criteria for food processing equipment. Lelieveld & Holah (2014) found that imperfections on food processing equipment posed a risk of accumulation of food residues during production and which subsequently support microbial growth. This is indicative that the equipment in use by the enterprises have a risk of accumulating food residues and providing conducive environments for growth and multiplication of both spoilage and pathogenic microorganisms.

To select the most appropriate materials of construction and designs for food processing equipment, manufacturers must have knowledge of the physical, chemical and thermal behaviour of materials as well as hygienic characteristics. Moerman & Partington (2014) assert that the manufacturers must also have insights in the laws, regulations, standards and guidelines applicable to the sector specific equipment to ensure compliance. Some of the common features of the product contact surfaces with imperfections among the respondents included loops in the piping system, folds on handles of plastic holding jerricans and bottom bases of plastic tanks, pits and crevices among others. Schlisselberg & Yaron (2013) found that surfaces have a potential to harbour bacterial cells and are hard to clean if they have high peaks and cracks, suggesting that surface finish is a critical factor in fabrication of food processing equipment.

In summary, a higher percentage of enterprises did not comply with the hygienic design criteria at 48% compared with those who complied at 36% as shown in Figure 4.7. This agrees with the findings that the majority of respondents had no knowledge of existing criteria or what the hygienic design criteria entailed and only half had technical competence, having been trained in food related courses. The low level of compliance is also probably due to the regulatory framework which does not include enforcement of specified requirements and guidelines on equipment design.

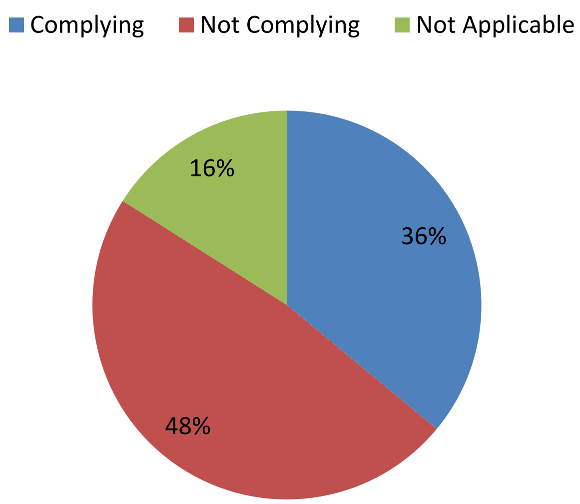


Figure 4.7: Summary of Compliance to Hygienic Design Criteria

4.3 EQUIPMENT CLEANING REGIMES AND HYGIENE PRACTICES

The results discussed here represent study objective number 3.

4.3.1 Equipment Cleaning Regimes

The cleaning regime of majority of the enterprises (56%), involved Cleaning-Out-of-Place (COP) using manual methods with either liquid soap or powdered multi-purpose soap as the main aids. Only 11% applied Cleaning-in-Place (CIP) method which combined both acid and lye (nitric acid and sodium hydroxide) as detergents. 11% of the respondents applied CIP using sodium bi carbonate, one of whom used the bicarbonate and vinegar to clean the internal parts of equipment and antiseptic solution (Dettol) for the external parts. Another 6% used hypochlorous2 solution (anolyte water) in a COP cleaning regime. The cleaning regime for 17% of the respondents involved rinsing of the processing equipment using water only, with one of them using the water at ambient temperature and two using hot water at unspecified temperatures. The study revealed that apart from the 11% of enterprises who employed CIP cleaning regime, temperature of water and contact duration between detergents and equipment was not factored in by the respondents during cleaning.

For those who applied COP, cleaning was generally carried out using manual scrubbing of internal and external surfaces of equipment with the aid of materials such as brushes and scouring pads. On the regularity of cleaning, 67% of the sampled enterprises cleaned both before and after processing with rinsing only carried out before commencement of production. 22% cleaned once, after processing, while 6% cleaned before processing only and another 6% before, after and continuously during processing.

While 72% of the respondents cited no constraints during cleaning, 28% pointed out some challenges which included inaccessibility of some machine parts, power outages and unreliability of water supply by the local authorities. 6% indicated that the water from the local authority had residues on some occasions. With reference to inaccessibility of equipment parts, the respondents indicated challenges such as pumps requiring specialized tools and technical personnel to dismantle. In addition, some parts such as sieves between the holding tank and pasteurizer were not fully accessible to circulating fluids during CIP, hence requiring dismantling for manual COP. This is consistent with the results of the assessment of compliance to EHEDG hygienic design criteria which showed that a higher percentage of assessed enterprises either partially complied or did not comply with the hygienic design criteria at 48% compared with those who fully complied at 36%.

Evans *et al.,* (2004) suggest that the microbial load on food contact surfaces varies from one food plant to another, depending on the microbiological quality of the food processed and the cleaning regimes in place. Gibson *et al.,* (1999) found that cleaning reduces the microbial load from these surfaces. However, the study revealed that the microbial residue was still in significant quantities even after cleaning, indicating that disinfection post-cleaning is critical. Majority of the respondents (77%) did not use any disinfectant after cleaning.

4.3.2 Source of Cleaning and Processing Water

All the enterprises sourced their processing and cleaning water from the local authorities (county government) supply, while 11% additionally used borehole water from within their premises as back-up in the event of rationing. One of the respondents (C15) in addition to water from the local authority used that supplied with tankers by private water vendors (usually borehole water). All the sampled enterprises used the water from local authorities directly with no further treatment. The respondents using borehole water carried out purification through a Reverse Osmosis (RO) system. Then 28% of the respondents cited the presence of residues in water from the local authorities as a cleaning constraint. This agrees with the findings of Matuszek (2013) who found that many food factories purchase their water supplies directly from local authorities, which may require further treatment before use. This presents a risk of cross contamination of the processing equipment and subsequently food products. Potability of water used for processing and cleaning in a food processing facility is therefore critical. Introduction of contaminated water into the processing plant may result in off-flavours, odours and off-tastes in food products and processing equipment, as well as contamination of food products with both spoilage and pathogenic microorganisms (Matuszek, 2013).

4.3.3 Verification of Cleaning and Sanitizing Processes

Only 6% companies (C2) carried out verification of cleaning effectiveness through in house analysis of water rinses for yeast and moulds and Total Viable Count (TVC), in addition to analysis of detergent (caustic) residues from the CIP process and visual inspection. Hofmann & Rugh (2014) suggest that methods for testing the effectiveness of cleaning of food processing equipment involves undertaking cleaning and measuring residual microorganisms still present on the surface after cleaning. 67% of the companies relied on visual inspection only as a verification for effective cleaning. 11% combined visual inspection with analysis of water rinses for detergent residues while 6% carried out P^H test to ensure neutrality in addition visual inspection. On the other hand, a few of the enterprises (11%) indicated that they did not carry out any form of verification.

Cleaning and sanitizing of food processing equipment must be effective to prevent contamination of the products with food residues, soil and microorganisms. The effectiveness is determined by including methods of validating that the procedures in place result to hygienic food contact surfaces. Visual inspection with the naked eye is an inexpensive method largely preferred by majority (67%) of the enterprises to survey surface cleanliness instantly, as shown by the study. However, the method is limited by human factors such as attention span and visual acuity thereby making it ineffective (Wiederoder, Lefcourt, Kim, & Lo, 2012). This is in agreement with the findings of Tebbutt *et al.,* (2007) who found that visual inspection alone may not be adequate to assess surface cleanliness, since surfaces that appear visually clean may have residual food debris and microorganisms, which may cause contamination of the food products.

4.3.4 Monitoring of Cleaning Procedures

Apart from 11% who used cleaning checklists and log sheets respectively to monitor implementation of cleaning regimes, the majority, 89%, did not maintain any form of records. This implies that cleaning and sanitizing is not monitored by most of the enterprises as part of verification of effectiveness.

4.4 RESIDUAL MICROBIAL ACCUMULATION ON PERSONNEL AND IN THE PROCESSING EQUIPMENT

The results discussed here represent study objective number 4.

Escherichia coli was detected in the hands of one food handler at C11 and *Staphyloccus aureus* in the hands of one food handler at C15. This is indicative of poor personnel hygiene practices and a potential source of cross-contamination to the equipment and food products. Humans are known to be conveyance of transient microorganisms in the food processing environment. Personnel hygiene practices and behaviours therefore play a critical role in elimination of microbial food safety hazards during food handling.

Escherichia coli was also detected in food contact surfaces (processing equipment) in 8 of 17 of the enterprises (47%) as shown in Table 4.6. *Pseudomonas aeruginosa* was detected on surfaces of equipment of 18% of the enterprises (C5, C9 and C15), whereas it should be absent while *Listeria monocytogenes* was not detected.

Majority of the enterprises had high counts of coliforms (71%), TVC (88%) and *Enterobacteriaceae* (71%) which were above the recommended limits as shown in Table 4.6 and Figure 4.8[1]. Only 12% (C2 and C4) of the enterprises fully met the microbial limits for the food contact surfaces while 6% (C16) met the limits for *Enterobacteriaceae* and Coliforms (below 10cfu/cm^2).

Table 4.6: Percentage (%) of enterprises with microbial levels above the acceptable limits in the hand swabs, food contact surfaces and end products

Microorganism	Hand swabs (%)	Food contact surfaces (%)	End product (%)
Escherichia coli	6	47	Not detected
Staphylococcus aureus	6	*	Not detected
Pseudomonas aeruginosa	*	18	Not detected
Listeria monocytogenes	*	Not detected	Not detected
Enterobacteriaceae	*	71	Not detected
Coliforms	*	71	6
Total Viable Count (TVC)	*	88	24

**** Microorganism was not analyzed.***
The numerical values indicate the % of enterprises.

[1] The limit of Coliforms, *Enterobacteriaceae* and TVC was set at 100cfu/cm^2 for purposes of graphical presentation. The range of the loads was between 0 and >30,000cfu/cm^2.

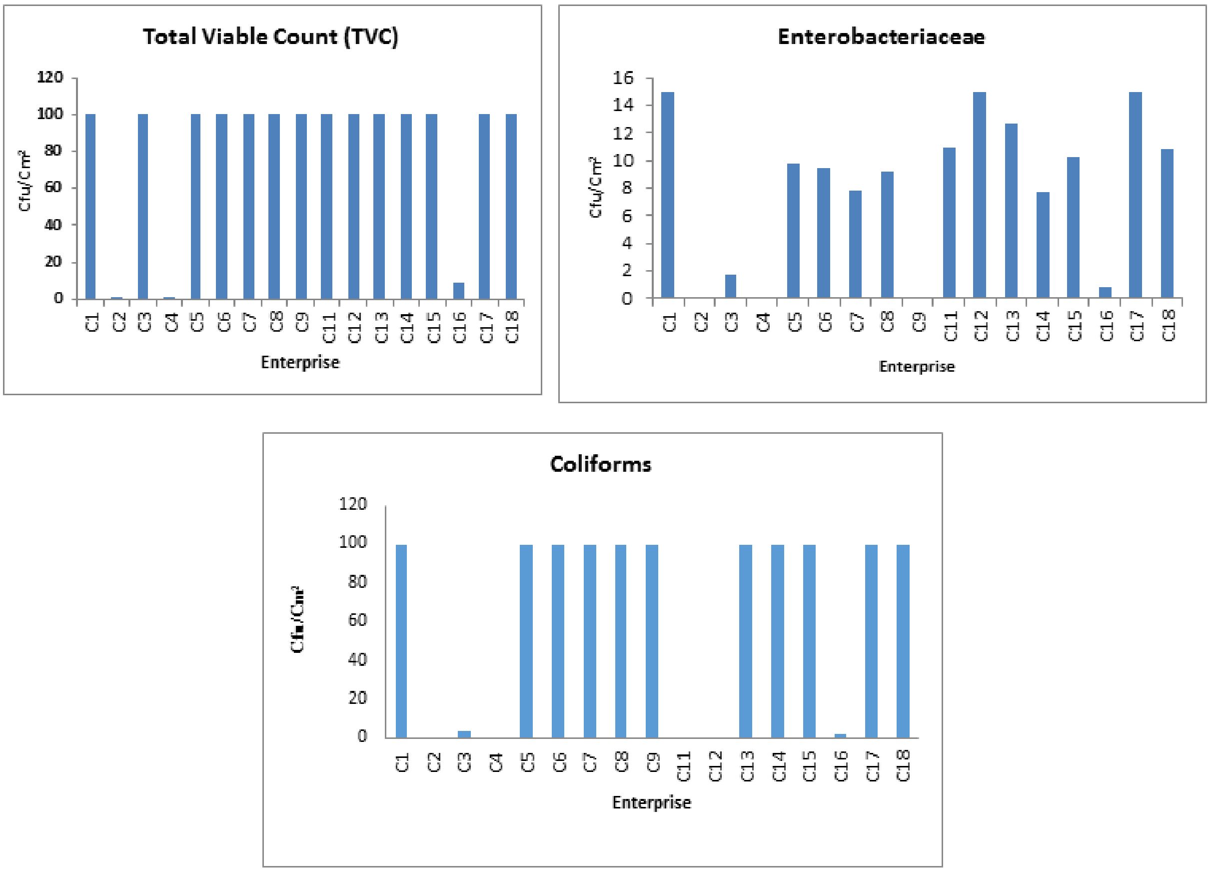


Figure 4.8: Performance of the processing equipment with levels of TVC, Coliforms and *Enterobacteriaceae*

Soft drinks and especially fruit juices are susceptible to microbial spoilage and may support growth of pathogenic microorganisms. Rapid deterioration as a result of subsequent chemical and physical changes may occur more so if the product is not pasteurized (Ashurst, 2011). This implies that presence of microbial contamination on food processing equipment is a potential source of transfer of pathogens into food (Wiederoder et. al, 2012), resulting in occurrence of food safety hazards.

Sampling food processing environments such as equipment is a useful way of validating and verifying effectiveness of cleaning and sanitizing procedures. Most methods used to estimate effectiveness of cleaning and surface contamination rely mostly on microbiological indicators, which gives an indication of food surface hygiene and is therefore key in prevention of cross-contamination and ultimately food spoilage and food borne illnesses (Verran *et al.*, 2002).

Holah et. al (2002) confirmed in a three year study period that there were persistent strains of *Listeri monocytogenes* and *Escherichia coli* in the UK food industry, and recommended for selection of suitable control options, including use of biocides to arrest the situation. Presence of *Escherichia coli* suggests faecal contamination which could have been from human contact or raw material and is of great concern as it poses a risk of pathogenesis in the event that the food product is contaminated. Holah *et al.*, (2002) suggests that ineffectiveness of cleaning regimes could also be attributed to the ability of microorganisms to resist disinfection at lower temperatures which are often associated with high risk.

Although microbiological specifications for food and hand-contact surfaces are not documented, guidelines exist indicating that counts above 10cfu/cm^2 are generally unacceptable for clean ready-to-use equipment surfaces (Tebbutt *et al.*, 2007). For example, the European Community (Commission Decision 2001/471/EC 2001) guidelines provides that cleaned and disinfected surfaces such as in meat establishments, should have less than 10 Coliform Forming Units (CFU) per cm^2 for total viable counts (TVC). Similarly, the US Public Health Service has put forward the same recommendation, with a stringent target of <2.5 CFU/cm^2 being applied in various food premises to minimize risks of exceeding the set maximum limits.

The poor performance in *Enterobacteriaceae* in the companies is an indication that cleaning and sanitation programmes in place are not effective and hence do not achieve the desired outcome. Similarly, presence of high total coliforms gives an indication of general poor cleaning standards which require greater attention during inspection, both during internal quality control and quality assurance by the regulatory authorities. TVC gives a general description of the measure of bacteria on the surface of the equipment, and include bacteria arising from both the product and the processing environment. The high counts in the equipment of the enterprises under study are therefore indicative of the level of the overall residual microbial population covering both spoilage and pathogenic organisms.

The findings are consistent with the level of compliance to the EHEDG criteria and the cleaning regimes employed by majority of the companies. The microbiological performance of the food contact surfaces of the enterprises can be attributed to the fact that majority of enterprises did not comply with the hygienic design criteria at 48% compared with those who complied at 36%. This is in agreement with Lelieveld & Holah (2014) who found that ineffective cleaning regimes leaves food residues in unhygienic surface features such as pits and crevices, that encourages growth of microorganisms harboured to sufficient numbers that can affect safety and quality of food.

The cleaning and sanitizing regimes employed by the majority of the enterprises are inadequate to ensure food safety. The regimes, as established by the study, do not follow the recommended procedures for effective cleaning which involve cleaning and disinfecting post cleaning, and largely rely on visual inspection as a method of verifying effectiveness of cleaning. Difficult to reach spaces such as valves, crevices and grooves are favourable breeding sites for microorganisms which compromise effectiveness of cleaning and sanitizing (Mafu *et al.,* 2011). Miguel *et al.,* (2012) assert that when microbial contamination levels are high and sanitization procedures inadequate, transient microorganisms multiply, establish themselves and become resident as biofilms, increasing their resistance to sanitizing agents.

The compliance of enterprises C2, C4 and C16 can be attributed to a number of factors. Production for all the three enterprises was manned by Quality Assurance Managers with Bachelor of Science in Food Science and Technology, hence technically competent. In addition, C2 and C16 are the only enterprises that had elaborate CIP systems utilizing acids and lye as detergents and hot water for sterilization post-cleaning.

The verification activities of C2 in addition to visual inspection included in-house analysis of water rinses for CIP caustic residue, yeast and moulds and TVC. Enterprise C16 carried out visual inspection and analysis of water rinses for detergent residues only. This explains its non-compliance with TVC since verification activities are not as adequate as compared to those employed in enterprise C2 to facilitate implementation of corrective action. C4 is the only enterprise that processed fruit flavoured drink in solid (dry powder) form which may be attributed to the microbiological performance of its product contact surfaces. Dry products (low water activity) do not support growth of most microorganisms. The microbiological performance of C2 and C16 is also attributed to their high level of compliance to the hygienic design criteria for equipment.

The two enterprises fully complied with the highest number of the fourteen EHEDG requirements. C2 partially complied with three of the requirements and fully complied with the remaining eleven while C16 fully complied with ten requirements, partially complied with three and did not comply with one of the requirements. This implies that the compliance of the equipment to the hygienic design criteria and application of elaborate cleaning and sanitizing procedures ensures microbial safety of food contact surfaces.

Samples of the final products were analysed in 12 out of the 17 enterprises against the requirements specified in the relevant Kenya and East African standards. The products in all the 12 enterprises complied with the requirements with regard to *Escherichia coli, Pseudomonas aeruginosa, Listeria monocytogenes, Enterobacteriaceae and Staphyloccocus aureus* which were not detected. End products from four of the enterprises, i.e. C5, C9, C15 and C16 had Total Viable Counts (TVC) above the specifications of the standards, while coliforms were detected in C5 which the standard requires to be absent. This is indicative of likely cross-contamination from the product contact surfaces which had coliforms above recommended levels. The TVC in the product contact surfaces in all the four enterprises were also above the recommended limits.

However, the general compliance of the end products with microbial limits is inconsistent with the rest of the findings. This could be attributed to other factors and variables beyond the scope of this study such as use of high levels of preservatives which would suppress the growth of microorganisms.

CHAPTER FIVE: CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

The conclusions of the study are given in order of the study objectives.

Characterization and product diversity of Micro and Small Enterprises

Majority of the enterprises were of the small category, with employee population of ten to fifty and turnover rates of over five hundred thousand but less than five million shillings. Further, most of the enterprises seemed to be specializing in the fruit flavoured drinks and fruit-based soft drinks, with majority processing only one type product. Only half of the enterprises had technical competence with personnel having background training in food related courses.

The regulation of the enterprises by the authorities is also not uniformly applied across the enterprises, including the regularity of visits. There is duplication of roles and overlaps, with none of the enterprises being regulated for compliance of processing equipment to hygienic design criteria. This agrees with the research hypothesis that the Micro and Small Enterprises in the soft drink industry in Nairobi metropolis are of varying characteristics and process diversified soft drink products.

Hygienic design and considerations in selection of food processing equipment

Majority of Micro and Small enterprises in the soft drink industry use processing equipment that do not comply with the hygienic design criteria. The enterprises use various types of equipment that are either locally improvised or fabricated without hygienic design considerations. Cost is the main factor of consideration for most of the enterprises in selection of the equipment with little or no consultation of technical expertise, and majority are not aware of the existence of the hygienic design requirements. Ineffective enforcement of regulations by the relevant regulatory authorities as depicted by the study also contributes to the non-compliances. The findings therefore agree with the research hypothesis that Micro and Small enterprises in the soft drink industry in Nairobi metropolis do not comply with the hygienic design considerations during selection of processing equipment.

Cleaning and Sanitizing of Food Processing Equipment by the Enterprises

Cleaning and sanitizing regimes employed by the majority of Micro and Small enterprises in the soft drink industry are not adequate to ensure food safety. The regimes do not follow the recommended procedures for effective cleaning, which involve cleaning and disinfecting post cleaning, and mostly rely on visual inspection as a method of verifying effectiveness of cleaning. Ineffective cleaning and disinfection of food contact surfaces presents a significant contamination risk factor, since dirty surfaces are potential sources of both pathogenic and spoilage microorganisms. This is in agreement with the research hypothesis that the cleaning regimes employed by the Micro and Small Enterprises in the soft drink industry in Nairobi metropolis do not conform to the accepted equipment cleaning best practices.

Microbiological Status of Processing Equipment and Products

Microbiological residue of food contact surfaces among the majority of the Micro and Small enterprises in the soft drink industry does not meet the desired levels. Majority of the enterprises present counts of coliforms, Total Viable Count and *Enterobacteriaceae* which are above the recommended limits. The high total counts in the equipment are indicative of the level of the overall residual microbial population covering both spoilage and pathogenic organisms and subsequently presents a potential for cross contamination of food products. The findings support the hypothesis that the extent of post-cleaning microbial accumulation in the processing equipment used by Micro and Small Enterprises in the soft drink industry in Nairobi metropolis is above the acceptable limits.

General Conclusions

Products from Micro and Small enterprises are potentially risky in terms of microbiological safety as a result of the choice of processing equipment and hygiene practices. A strange phenomenon was observed, where some of the final products fully complied with the microbiological requirements yet the level of microbial contamination on the equipment was above the recommended safe levels. The consistency of quality and safety of production processes and of the products from this subsector is therefore not assured.

The enforcement of requirements by the regulatory authorities is inadequate and does not focus on some key aspects such as compliance to the hygienic design criteria, cleaning and sanitizing procedures in place and verification activities employed by the Micro and Small enterprises. There is also duplication of regulatory roles as seen by the work carried out by Kenya Bureau of Standards and Department of Public Health which may be attributed to the ineffectiveness of enforcement of some specified requirements.

The assessment has given clear indication that there is a direct link between hygienic design of food processing equipment, effectiveness of cleaning and sanitizing and microbial safety of food products.

5.2 Recommendations

It is recommended that the Micro and Small Enterprises in the food industry be trained to improve cleaning and sanitizing procedures which include verification of effectiveness of cleaning regimes in place. This can be carried out either by in-house or group trainings of individual enterprises or by encouraging collaboration, and by enforcing adherence to the Good Manufacturing Practices (GMPs).

There is need for development of standard operating procedures and work instructions, retraining of production staff, evaluation of maintenance of equipment and improvement of in-house supervision among the enterprises.

On the regulatory framework, legislation on hygienic design of processing equipment and hygiene practices needs to be enhanced to ensure food safety. This can be achieved by development of a cleaning and sanitizing code of practice which should be applied as part of local authority inspections. To ensure effectiveness of enforcement, awareness of hygienic design criteria and equipment cleaning, the authorities need to carry out extensive awareness of the requirements to food industry stakeholders, including manufacturers and suppliers of processing equipment. There is also need for development of policies that enhance capacity building among the Micro and Small enterprises in line with the Kenya vision 2030 flagship project.

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APPENDICES

Appendix 1: Questionnaire

PROCESSING EQUIPMENT SELECTION AND HYGIENE PRACTICES QUESTIONNAIRE

INTRODUCTION

The survey covers areas on processing equipment selection criteria and hygiene practices by the Micro and Small enterprises in the soft drinks and fruit juice industry. Please answer every question. If you are uncertain about how to answer a question, do not hesitate to ask for clarification.

Respondent's Name (Optional):____

Job Title:____

Telephone No: ___________________________Email Address:____________________________

Date of Interview

Day	Month	Year
		2016

SECTION A: INFORMATION ABOUT THE ORGANISATION

Tick as appropriate

i. Please indicate the number of employees and the organization's annual turnover in Kenya Shillings (KES.).

No. of Employees		Annual turnover (KES.)	
Less than 10		Less than KES. 500,000	
10 to 50		KES. 500,000 to 5Million	

ii. Kindly indicate the different types/categories of products produced in your factory.

Cordials/drinks	
Nectar/fruit juice blends	
Juices (specify e.g. mango)	
Fruit based soft drinks	
Fruit flavoured drinks (specify e.g. fruit flavoured milk)	
Others (Specify)	

iii. Please specify your average daily production (In litres)

10 - 200	
201 - 300	
301 – 400	
Above 400	

iv. Type of equipment used for processing.

	Name of equipment	Brand/Manufacturer	Country of Origin	Supplier
1.				
2.				
3.				
4.				
5.				
6.				
7.				

v. Please indicate your Considerations for selection of equipment. (Select all that apply)

Cost	
Advised by a technical person	
Advised by a friend/acquaintance	
Ease of use and cleaning	
Other (Specify)	

vi. Is there an equipment service/ maintenance programme in place? | Yes | No |

If yes, please specify-

____

vii. Kindly indicate any constraints encountered while purchasing food processing equipment

____
____
____
____
____

SECTION B: HYGIENE PRACTICES

- Cleaning regime.

1. Describe method (including detergents used for cleaning.

____
____
____
____

Tick as appropriate

2. Source of cleaning water.

Local authority e.g. Nairobi Water and Sewerage Company	
Borehole	
Other sources (Specify)	

3. Regularity of cleaning of equipment.

Before processing	
After processing	
Before and after processing	
Only during processing	
Before, after and during processing	

- Kindly indicate any constraints encountered while cleaning the equipment.
  ____
  ____
  ____
  ____
  ____

SECTION C: REGULATORY AUTHORITIES

Kindly indicate the bodies/authorities that carry out regulatory (inspection) work in your factory.

Regulatory body	Regulation	Type of work	Remarks

Awareness of hygienic design criteria____

Verification of cleaning____

Documentation____

Any other comment:

____
____
____
____
____

Thank you for filling the questionnaire. Your effort is highly appreciated.

Appendix 2: Equipment Design Checklist: European Hygienic Engineering and Design Group (EHEDG)

CLAUSE	STATEMENT OF REQUIREMENT	STATUS OF CONFORMANCE			REMARKS
		Complying (C)	Not Complying (N)	Not Applicable (NA)	
6	**Hygienic design and construction**				
6.2	**Surfaces and geometry**				
6.2.1	Equipment and pipe connections are aligned.				
6.2.2	Product is not in contact with screw threads.				
6.2.3	All surfaces in contact with the product are easily accessible for visual inspection and manual cleaning.				
6.3	**Surface finish/surface roughness**				
6.3.1	Product surfaces are free of imperfections such as crevices, pits, folds and surface ruptures.				
6.3.2	Type of food contact surface e.g. steel				
6.4	**Drainability and Layout**				
6.4.1	The exterior and interior parts of equipment are self-draining				
6.4.2	Surfaces slope to one side i.e. horizontal surfaces are avoided				
6.5	**Installation**				
6.5.1	The risk of condensation on equipment, pipework				

	and internal surfaces of the building are avoided				
6.5.2	Condensate diverts away from the product (where the above is unavoidable).				
6.5.3	Equipment and support structures are sealed to the supporting surface (floors, walls, columns, ceiling) in such a way that no pockets or gaps exist.				
6.5.4	Any clearance between equipment and civil construction (floors, walls and ceiling) is adequate for cleaning and inspection.				
6.6	**Welding**				
	Permanent metal to metal product contact joints are continuously welded and free of imperfections.				
6.7	**Supports**				
	Supports for piping or equipment are fabricated and installed such that no water or soils can remain on the surface within the supports.				
6.8	**Insulation**				
	Insulation materials are clad with stainless steel, which is fully welded such that no ingress of air or moisture is possible.				

Appendix 3: Informed Consent Form

INFORMED CONSENT FORM

Research Title: *Adherence to hygienic design in the selection of processing equipment by the small and medium enterprises in the soft drinks and fruit juice industry in Nairobi, Kenya*

Researcher

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The study is an academic project that endeavors to establish the impact of equipment design on microbial contamination in the soft drinks and fruit juice industry. The findings from this research will benefit a number of stakeholders including, government regulators, food processors, researchers in the field of food safety and consumers.

All the information you will provide will be used for the purposes of this study and will be treated with utmost confidentiality without any reference to you or the name of your business.

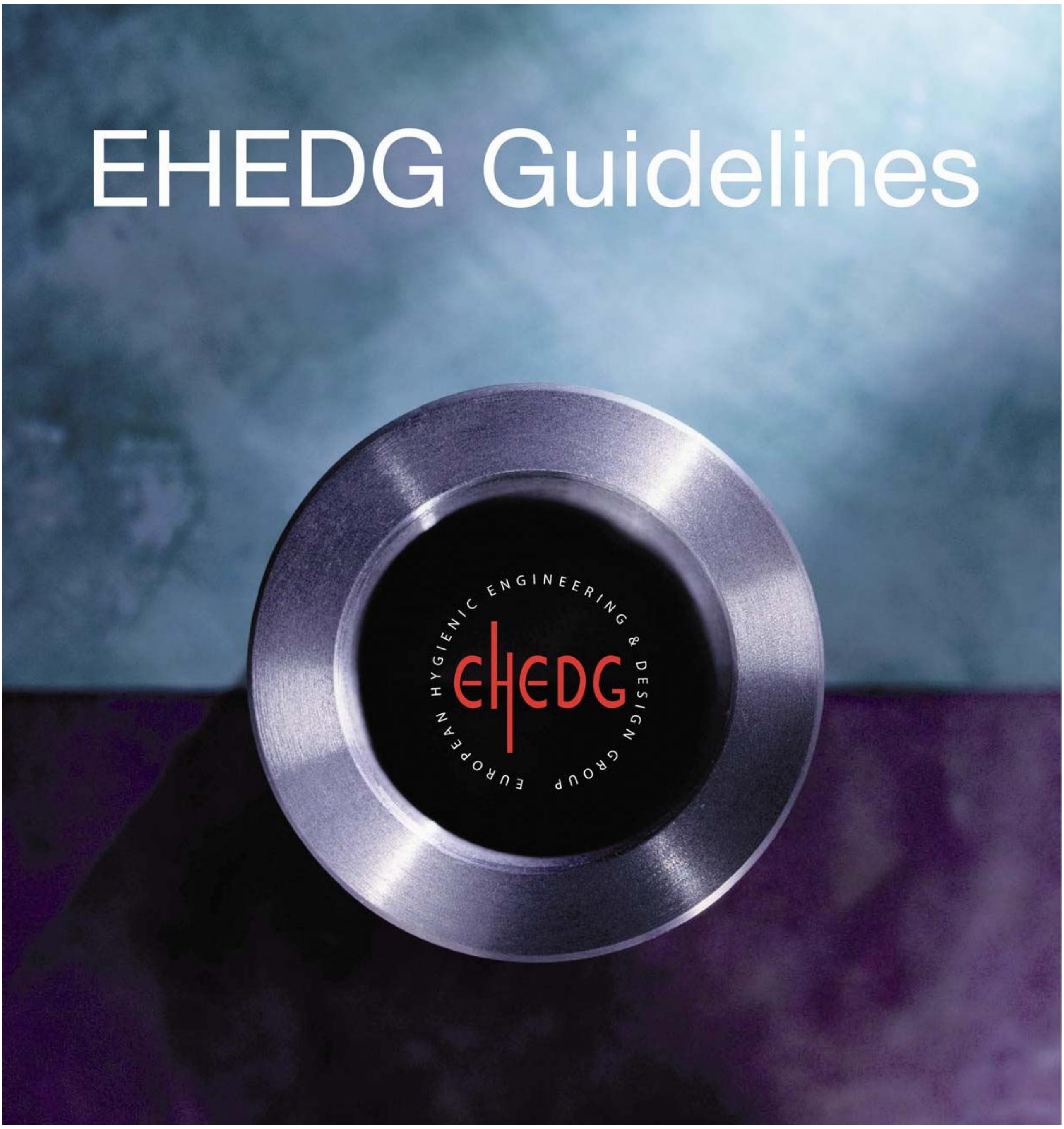
To the respondent:	**Please Tick**
1 I confirm that I have read and understand the information provided for the above study and have had the opportunity to ask questions.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.	☐
3. I agree to take part in the above study.	☐

Respondent: Signature:

Researcher: Signature:

Date: ________________________________

Appendix 4: European Hygienic Engineering and Design Group Guidelines: Hygienic Equipment Design Criteria of 2004



DOC 8

HYGIENIC EQUIPMENT DESIGN CRITERAI

Second edition, April 2004

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Contents

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HYGIENIC EQUIPMENT DESIGN CRITERIA*

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* Update prepared by the Subgroup "Design Principles" of the European Hygienic Engineering and Design Group (EHEDG), April 2004

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Introduction

This document describes the criteria for the hygienic design of equipment intended for the processing of foods. Its fundamental objective is the prevention of the microbial contamination of food products. Such contamination may, of course, originate from the raw materials, but the product may also be contaminated with micro-organisms during processing and packaging. If equipment is of poor hygienic design, it will be difficult to clean. Residues (soil) may be retained in crevices and dead areas, allowing the micro-organisms which they harbour to survive and multiply. These may then cross-contaminate subsequent batches of product.

Although a primary objective of design remains that the equipment is able to fulfil its engineering function, sometimes the requirements of hygiene will conflict with this. In seeking an acceptable compromise it is imperative that food safety is never put at risk.

Upgrading an existing design to meet hygiene requirements can be prohibitively expensive and may be unsuccessful and so these are most effectively incorporated into the initial design stage. The long-term benefits of doing so are not only product safety but also the potential to increase the life expectancy of equipment, reduce maintenance and consequently lower operating costs.

This document was first published in 1993 with the intention to describe in more detail the hygienic requirements of the Machinery Directive (89/392/EEC superseded by 98/37/EC; *ref. 1*). Afterwards parts of it have been included in the standards EN 1672-2 and EN ISO 14159.

1 Objectives and scope

This document details the principal hygienic design criteria to be met by equipment for the processing of foods. It gives guidelines on how to design, construct and install such equipment so that it does not adversely affect food quality; especially safety. The guidelines apply to durable equipment used for batch and continuous, open and closed manufacturing operations.

The susceptibility of the product to microbial activity will determine the balance between normal engineering demands and those of hygiene. For example, dry products do not support the growth of micro-organisms and requirements will be more relaxed than for moist products. However, if the equipment is to be used for products destined for 'at-risk' consumer groups, the hygiene demands on design will be more stringent. Here the designer may need to consult appropriate authorities such that the right balance is achieved.

2 Normative references

The following documents contain provisions that, through reference, constitute provisions of this EHEDG Guideline. At the time this Guideline was prepared, the editions listed below were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent editions of the documents indicated below.

EN 1672-2:1997 Food processing machinery – Basic concepts – Part 2: Hygienic Requirements EN ISO 14159:2002 (E) Safety of machinery – Hygiene requirements for the design of machinery

3 Definitions

The definitions in the EHEDG Glossary (see www.ehedg.org/glossary.pdf) apply to this guideline. The most relevant definitions specific to hygienic equipment design are:

Product contact surface

All equipment surfaces that intentionally or unintentionally (e.g. due to splashing) come in contact with the product, or from which product or condensate may drain, drop or be drawn back into the main product or product container, including surfaces (e.g. unsterilised packaging) that may indirectly cross-contaminate product contact surfaces or containers. A risk analysis can help to define areas of cross contamination.

Non-product contact surface

All other exposed surfaces.

Non-toxic construction materials

Materials which, under the conditions of intended use, do not release toxic substances.

Non-absorbent materials

Materials which, under the conditions of intended use, do not internally retain substances with which they come into contact.

Conditions of intended use (for the equipment)
All normal or reasonably anticipated operating conditions, including those of cleaning. These should set limits for variables such as time, temperature and concentration.

4 Materials of construction

4.1 General

Materials used in the construction of food machinery must fulfil certain specific requirements. Product-contact materials must be inert both to the product and to detergents and disinfectants under the conditions of intended use.

They must also be corrosion resistant, non-toxic, mechanically stable, and their surface finish must not be adversely affected under the conditions of intended use. Non-product-contact materials shall be mechanically stable, smoothly finished and easily cleanable.

It is worthwhile maintaining an awareness of new developments in materials and products for the food industry and seeking the advice of materials suppliers where appropriate.

4.2 Non-toxicity

As the presence of toxic elements in the food is unacceptable, the designer has to take care that only non- toxic materials of construction are used in direct contact with the product. It is imperative to check legislative aspects – many countries have codes of practice and directives covering the composition of materials in contact with foodstuffs and it should be ensured that the use of a specific material is permitted under existing or pending legislation *(ref. 2)*.

Stainless steels are the logical choice for materials of construction for process plant in the food industry but, depending on the application, some polymeric materials may have advantages over stainless steel such as lower cost and weight or better chemical resistance. However, their non-toxicity, and those of materials such as elastomers, lubricants, adhesives and signal transfer liquids, must be assured.

4.3 Stainless steel

Generally stainless steels offer excellent corrosion protection, and they are therefore widely used in the food industry. The range of stainless steels available is extensive and the selection of the most appropriate grade will depend on the corrosive properties (in terms not only of the chemical ions involved but also the pH and the temperature) of the process and of the cleaning and antimicrobial chemicals. However, the choice will also be influenced by the stresses to which the steel will be subjected and its machinability, formability, weldability, hardness and cost.

Where good resistance to general atmospheric corrosion is required, but the conditions of intended use will involve only solutions with a pH of between about 6·5 and 8, low levels of chlorides (say, up to 50mg/l [ppm]) and low temperatures (say, up to 25ºC), the most common choice would be AISI-304, an austenitic 18%Cr/10%Ni stainless steel, or its low-carbon version AISI-304L (DIN 1.4307; EN X2CrNi18-9), which is more easily welded.

If both the level of chlorides and the temperature exceed approximately double these values, the material will require greater resistance to the crevice- and
pitting-corrosion which may result from chlorides concentrating locally. The addition of molybdenum to AISI-304 (creating AISI-316) improves its corrosion-resistance and this grade of stainless steel is recommended for components such as valves, pump casings, rotors and shafts, while its low-carbon equivalent AISI-316L (DIN 1.4435; EN X2CrNiMo18-14-3) is recommended for pipework and vessels due to its enhanced weldability. Alternatively, titanium may be appropriate.

As temperatures approach 150ºC, even AISI-316 stainless steels may suffer from stress-corrosion cracking where regions of high stress are exposed to high levels of chloride. Here AISI-410, AISI-409, AISI-329, or even Incoloy 825 *(ref. 3)* may be required for their high strength and/or high corrosion resistance, although they may be more costly.

AISI, DIN and EN designations of stainless steels commonly used in the food industry are given in Table 1.

Table 1 — AISI, DIN and EN designations of stainless steels commonly used in the food industry

	DIN/EN	Typical analyses

	DIN 1.4307 (EN X2CrNi18-9)						
	DIN 1.4435 (EN X2CrNiMo18-14-3)						
	DIN 1.4006 (EN X12Cr13)						
	DIN 1.4512 (EN X2CrTi12)						
	DIN 1.4460 (EN X3CrNiMoN27-5-2)						

Also see EHEDG Guideline on Materials of Construction (Doc. 32). Full specifications for non-cast stainless steels are available from AISI *(ref. 4)* and EN/DIN *(ref. 5)* and for cast stainless steels from ACI *(ref. 6)*.

4.4 Polymeric materials

When choosing polymeric materials the following criteria should be considered:

— Compliance with regulatory requirements and recommendations *(ref. 7, 8)*

— Compatibility with food stuffs and ingredients (chemical resistance to oil, fat, preservatives)

— Chemical resistance (cleaning and disinfectants)

— Temperature resistance in use (upper and lower use temperature)

— Steam resistance (CIP / SIP)

— Stress-crack resistance

— Hydrophobicity / reactivity of the surface

— Cleanability, effect of surface structure and smoothness, residue accumulation

— Adsorption / desorption

—

— Leaching

— Hardness

— Resilience

— Cold flow resistance

— Abrasion resistance

— Processing technology (injection moulding, melt-extrusion, transfer-moulding, paste-extrusion, welding, various coating technologies)

Polymers frequently used in hygienically designed equipment are:

— Acetal (Homo- and Co-Polymer) (POM)

— Fluoropolymers, e.g.:

— Ethylene-Tetrafluoroethylene Copolymer (ETFE)

— Perfluoroalkoxy Resin (PFA),

— Polytetrafluoroethylene (PTFE, modified PTFE)

— Polyvinylidene Fluoride (PVDF)

— Fluorinated Ethylene Propylene Copolymers (FEP)

— Polycarbonate (PC)

— Polyetheretherketone (PEEK)

— Polyether Sulfone (PESU)

— High Density Polyethylene (HDPE)

— Polyphenylene Sulfone (PPSU)

— Polypropylene (PP)

— Polysulfone (PSU)

— Polyvinyl Chloride, unplasticised (PVC)

If considering the use of Polytetrafluoroethylene (PTFE), it must be taken into account that PTFE can be porous and difficult to clean. But certain grades of modified PTFE and fully fluorinated co-polymers such as PFA have been proven to meet EHEDG requirements for cleanability.

Polymeric materials – like other materials of construction such as glass, steel and enamel – must be selected based on the conditions of intended use.

Certain polymers, particularly Fluoropolymers, can be applied as a coating material (thin layers from 50 µm to about 1.2 mm) on many metallic substrates to improve their chemical resistance or other surface related properties. Technologies to apply the coatings depend on the geometry of the component and it is advisable to discuss options with the raw material supplier and manufacturer. It is suggested that a food compliance statement be requested from the raw material manufacturer.

For further information and details on the temperature and chemical resistance of the various polymers listed above and the parts made thereof, please refer to the specific product data sheets and/or contact your part supplier or the polymer manufacturer directly.

4.5 Elastomers

The same parameters as listed in the 'polymeric materials' section above will apply for the selection of an elastomer. When it comes to finished parts then identification and traceability become important issues that need to be addressed. Compliance with FDA regulations can be covered through Food Contact Notification (FCN) certificates as well as conformity statements to 21 CFR 177.2600, for example.

The elastomer types that can be used in the food industry for seals, gaskets and joint rings are:

— Ethylene Propylene Diene Monomer (EPDM) *
— Fluoroelastomer (FKM)**
— Hydrogenated Nitrile Butyl Rubber (HNBR)
— Natural Rubber (NR)
— Nitrile/Butyl Rubber (NBR)
— Silicone Rubber (VMQ)**
— Perfluoroelastomer (FFKM)***

* EPDM is not oil and fat resistant

** also for temperature applications up to 180 °C

*** also for high temperature applications up to and above 300°C.

For further information and details on the suitability of the various elastomers listed above and the parts made thereof, please refer to the specific product data sheets and/or contact your part supplier or the elastomer manufacturer directly.

4.6 Adhesives

Adhesives used should always comply with the FDA regulations and with the recommendations of the supplier of the equipment for which those gaskets are used. This is required to ensure that the adhesive will not lead to localised corrosion attack of the stainless steel of the equipment or release toxic components under the conditions of intended use. All bonds must be continuous and mechanically sound, so that the adhesive does not separate from the base materials to which it is bonded.

4.7 Lubricants

Equipment should be designed such that lubricants do not come into contact with products. Where contact may be incidental lubricants should conform to the NSF Non-Food Compounds Registration Program. This supersedes the USDA product approval and listing program, which is based on meeting regulatory requirements including FDA 21 CFR for appropriate use, ingredients and labelling *(ref. 9)*. Further guidance on production and use of lubricants is available in EHEDG document No.23 *(ref. 10).*

These documents specify which components are allowed in oils and greases used for lubricating purposes, as protective anti-rust film, as release agent on gaskets and seals of tank closures, and as a lubricant for machine parts and equipment in locations where there is exposure of the lubricated parts to food or food ingredients.

4.8 Thermal insulation materials

Thermal insulation of equipment must be carried out in such a way that the insulation material cannot be wetted by ingress of water from the outside environment (e.g. hosing down, condensation on cold surfaces). The insulation material may not contain chloride. Ingress of water may otherwise lead to a build up of chloride on the stainless steel surfaces, resulting in stress corrosion cracking or pitting corrosion. Ingress of water may also result in loss of insulation performance.

4.9 Signal transfer liquids

Liquids used for signal transfer may come into contact with the process fluids if the barrier between them fails. Therefore these liquids must be food grade.

5 Functional requirements

Hygienic food processing equipment should be easy to maintain to ensure it will perform as expected to prevent microbiological problems. Therefore, the equipment must be easy to clean and protect the products from contamination. In the case of aseptic equipment, the equipment must be pasteurisable or sterilisable (depending on the application) and must prevent the ingress of micro-organisms (i.e. it must be bacteria tight). It must be possible to monitor and

control all of its functions which are critical from a microbiological safety point of view.

5.1 Cleanability and decontamination

Cleanliness is a very important issue. Equipment which is difficult to clean will need procedures which are more severe, require more aggressive chemicals and longer cleaning and decontamination cycles. Results will be higher cost, reduced availability for production, reduced lifetime of the equipment, and more effluent.

Ingress of micro-organisms into products must be avoided in general. Usually, it is desirable to limit the number of micro-organisms in food products as much as possible to meet requirements of public health and required shelf life.

Equipment intended for aseptic processes must additionally be impermeable to micro-organisms.

5.2 Prevention of growth of micro-organisms

Under favourable conditions micro-organisms grow very rapidly. Consequently any areas, e.g. dead areas, gaps and crevices, where micro-organisms can harbour must be avoided.

5.3 Compatibility with other requirements

A design with excellent hygienic characteristics but lacking the ability to perform its functional duties is of no use; hence a designer may have to compromise. Such action, however, will have to be compensated by more intensive cleaning and decontamination procedures and these must be documented so that the users are aware of the nature of the compromise. The cleanability of the equipment, including the CIP where appropriate, must be demonstrated.

5.4 Validation of the hygienic design of equipment

Irrespective of the amount of know-how and experience with hygienic design which is applied when designing and fabricating, practice has shown that inspection, testing and validation of the resulting design to check if the requirements are met is very important. In critical cases it may be necessary to check the hygiene level as part of the maintenance procedures. The designer has to make sure that relevant areas are accessible for inspection and/or validation.

6 Hygienic design and construction

6.1 General

In the design, fabrication and installation of equipment the following basic criteria must be taken into consideration:

6.2 Surfaces and geometry

Surfaces must be cleanable and must not present a toxicological hazard by leaching of components into the food. All product contact surfaces must be resistant to the product, and to all detergents and disinfectants under the full range of operating conditions (the intended conditions of use). Product contact surfaces must be made of non-absorbent materials and must satisfy the roughness requirements as specified under section 7.2 below.

Product contact surfaces must be free of imperfections such as crevices, therefore:

— Avoid direct metal to metal joints other than welding (metal to metal contact may harbour soil and micro- organisms). In the case of equipment intended for aseptic processing, the hazard also exists that metal to metal seals will not prevent the ingress of bacteria.

— Avoid steps due to misalignment in equipment and pipe connections.

— If seals or gaskets are used, their design must be such that no crevice exists where soil residues may be trapped and bacteria can accumulate and multiply.

— Unless deformed to obtain a flush static seal at the product side, the use of O-rings in contact with the product must be avoided in hygienic equipment and piping systems *(ref. 11)*. For appropriate O-ring design, see EHEDG document No. 16 *(ref. 12)*.

— Eliminate the contact of product with screw threads.

— Corners should preferably have a radius equal to or larger than 6 mm; the minimum radius is 3 mm.
Sharp corners (≤90°) must be avoided.

If used as a sealing point, corners must be as sharp as possible to form a tight seal at the point closest to the product/seal interface. In this situation a small break edge or radius of 0.2 mm may be required to prevent damage to elastomeric seals during thermal cycling.

If for technical and functional reasons any of these criteria cannot be met the loss of cleanability must be compensated in some way, the effectiveness of which must be demonstrated by testing.

All surfaces in contact with product must be either easily accessible for visual inspection and manual cleaning, or it must be demonstrated that routine cleaning completely removes all soil. If cleaning in-place (CIP) techniques are used, it must be demonstrated that the results achieved without dismantling, are satisfactory (see section 7.8 “Testing the hygienic characteristics of equipment”).

6.3 Surface finish / surface roughness

Product contact surfaces should have a finish of an acceptable Ra value and be free from imperfections such as pits, folds and crevices (for definition of Ra, see ISO 4287:1997). Large areas of product contact surface should have a surface finish of 0.8 µm Ra, or better, although the cleanability strongly depends on the applied surface finishing technology, as this can affect the surface topography.

It should be noted that cold-rolled steel has a roughness of Ra = 0.2 to 0.5 µm and therefore usually does not need to be polished in order to meet surface roughness requirements, provided the product contact surfaces are free from pits, folds and crevices when in the final fabricated form.
A roughness of Ra >0.8 µm is acceptable if test results have shown that the required cleanability is achieved because of other design features, or procedures such as a high flow rate of the cleaning agent. Specifically, in the case of polymeric surfaces, the hydrophobicity, wettability and reactivity may enhance cleanability *(ref. 13)*.
The relation between the treatment of stainless steel and the resultant surface topography is indicated in Table 2. It is the topography which governs the cleanability. Pits, folds, crevices, surface ruptures and

irregularities which have been peened over can all leave regions inaccessible to cleaning agents.

6.4 Prevention of ingress of micro-organisms

Table 2 — Examples of surface treatments of stainless steel and resulting surface topography

Surface treatment	Approx. Ra values (µm)	Typical features of the technique
Hot rolling	> 4	Unbroken surface
Cold rolling	0.2 - 0.5	Smooth unbroken
Glass bead blasting	< 1.2	Surface rupturing
Ceramic blasting	< 1.2	Surface rupturing
Micropeening	< 1	Deformed (peened)
Descaling	0.6 – 1.3	Crevices
Pickling	0.5 – 1.0	High peaks, deep
Electropolishing		Rounds off peaks
Mechanical aluminium carbide Abrasive grit number		Surface parameters, such as belt speed and pressure.
500	0.1 – 0.25	
320	0.15 – 0.4	
240	0.2 – 0.5	
180	≤ 0.6	
120	≤ 1.1	
60	≤ 2.5	

Non-product contact surfaces must be smooth enough to ensure that cleaning is easy.

6.5 Drainability and lay-out

The exterior and interior of all equipment and pipework must be self-draining or drainable and easily cleanable. Horizontal surfaces must be avoided; instead surfaces should always slope to one side. In the case of external surfaces, this should result in any liquid flowing away from the main product area.

6.6 Installation

The risk of condensation on equipment, pipe work and the internal surfaces of the building should be avoided wherever possible. If unavoidable, the design should be such that condensate is diverted away from the product.
Equipment and support structures must be sealed to the supporting surface (floor, walls, columns, ceiling) in such a way that no pockets or gaps exist.

Any clearance between equipment and the civil construction (floors, walls and ceiling) shall be adequate for cleaning and inspection *(ref. 14)*.

6.7 Welding

Permanent metal to metal product contact joints must be continuously welded and free of imperfections.
During welding, protection of both the torch side and the opposite side of the weld by an inert gas may be required. If carried out properly, the need for post welding treatments (grinding, polishing) will be minimised. For pipework, the preferred method is automatic orbital welding, which is capable of producing consistently high quality welds.

Welds on the non-product contact side must be continuous; they must be smooth enough to allow proper cleaning.

Detailed recommendations on welding to meet hygienic requirements are given in EHEDG document No. 9
(ref. 15).

6.8 Supports

Supports for piping or equipment must be fabricated and installed such that no water or soils can remain on the surface or within the supports. The possible adverse galvanic reactions between dissimilar materials should be taken into consideration.

6.9 Insulation

Options available for insulation of equipment and pipework are:

— Sealed cladding

Insulation materials should be clad with stainless steel, which must be fully welded, so that no ingress of air or moisture is possible, as this may encourage microbial growth and hence increase the risk of microbial contamination or corrosion of the cladding if the insulation materials release chlorides.

— Vacuum

Pipework can be insulated by evacuation of air in the shell of double walled pipe. This is a very effective way of preventing any of the problems listed.

6.10 Testing the hygienic characteristics of equipment

A series of EHEDG test methods for assessing the hygienic characteristics of equipment has been published.

— A method for assessing the in-place cleanability of food processing equipment, EHEDG Doc. 2 *(ref. 16)*

— A method for the assessment of in-line pasteurisation of food processing equipment, EHEDG Doc. 4 *(ref. 17)*

— A method for the assessment of in-line sterilisability of food processing equipment, EHEDG Doc. 5 *(ref. 18)*

— A method for the assessment of bacteria tightness of food processing equipment, EHEDG Doc. 7 *(ref. 19)*

— A method for the assessment of in-place cleanability of moderately-sized food processing equipment, EHEDG Doc. 15 *(ref. 20)*

7 References

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(5) EN 17 440: 2001. Stainless steels - Technical delivery conditions for drawn wire.

(6) Alloy Designations for Cast Stainless Steels. ASTM Standard A781/A781M, Appendix XI. Steel Founder's Society of America, Cast Metal Federation Bldg., 455 State St, Des Plaines, IL 60016, USA

(7) Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs

(8) Code of Federal Regulations, Title 21, (21 CFR) Part 170-199, Food and Drugs Administration

(9) NSF White Book Listing of Non-food Compounds (www.nsf.org/usda)

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(16) EHEDG Document[*)] No.2, *Third Edition (2004).* A method for the assessment of in-place cleanability of food processing equipment.

(17) EHEDG Document[*)] No.4 (1993). A method for the assessment of in-line pasteurization of food processing equipment. Also as an extended abstract in *Trends in Food Science & Technology* 4(2): 52-55

(18) EHEDG Document[*)] No.5, *Second Edition (2004).* A method for

the assessment of in-line steam sterilisability of food processing equipment.

(19) EHEDG Document[*)] No.7, *Second Edition (2004).* A method for the assessment of bacteria tightness of food processing equipment.

(20) EHEDG Document[*)] No.15 (1997). A method for the assessment of in-place cleanability of moderately-sized food processing equipment. Also as an extended abstract in *Trends in Food Science & Technology* 8(2): 54-57

[*)] Order information for all EHEDG documents can be obtained from the website www.ehedg.org (2004) Updated editions expected to be published later on.