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Impact of HACCP Based Food Safety Management Systems in Improving Food Safety of Sri Lankan Tea Industry

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Abstract A study was conducted to identify and assess the major food safety violations in low grown orthodox black tea manufacturing process while assessing impact of HACCP based food safety management system (FSMS) in tea industry. Stratified random sampling was used where qualitative data was weighted averaged against GMP requirements and converted in to quantitative values to be used in statistical analyses. The impact of HACCP based FSMS in improving food safety was evaluated using representative sample. Organization and management responsibility was strongly correlated with establishment design and facilities while quality assurance had a strong or moderate correlation with all the factors. Pest control and personal hygiene was not satisfactorily developed according to the results. Establishment design and facilities (ED&F) was the major root cause for the food hygiene problems identified where continuous attention and top management commitment as well as additional capital investments were needed to improve design and facilities of manufacturing plants in the sector. Similarly, Quality assurance systems were not in complete compliance with food safety, mostly due to the incomplete system developments, lack of expert knowledge in the industry as well as inappropriate practices. However, HACCP based FSMS have created enabling environment to improve GMP requirements while increasing food safety implementation in tea industry. Nevertheless, factories with HACCP based FSMS had better infrastructure and systematic operations with trained operators rather than factories without any HACCP based FSMS. The efficacy of processing, recording and personnel hygiene were satisfactorily improved in factories which had implemented HACCP based FSMS.
Keywords HACCP; FSMS; GMP; Tea industry; Orthodox black tea; Food safety

1 Introduction

The Sri Lankan tea industry has a long history spanning close to a century and a half to become the third largest agricultural crop in the country (Janaka and Swendrani, 2011) which provides over 1 million direct and indirect employments while generating significant amounts of foreign exchange (Institute of Social Development, 2008). In addition, country accounts for 9% share of world tea production and about 19% of total global tea exports (SOMO, 2008; Ministry of Plantation Industries, 2013). Sri Lankan tea industry annually produced around 320 million kilograms of made tea according to the current statistics available. Out of the given production output, country has manufactured approximately 95% black tea annually which basically intended for export representing 32% of the global demand on orthodox black tea (Ministry of Plantation Industries, 2013) where Sri Lanka is still the market leader for orthodox black tea (Janaka and Swendrani, 2011). The CTC and green tea represents only 5% of the total production and country manufacture tea throughout the year. The annual production contributed from various parts of the country with figures of low grown 60%, mid-grown 16% and high grown 24% respectively, while 95% of the produce were accounted as orthodox black tea (Department of Census and Statistics, 2012).

The country's major problem to the improvement in production and infrastructure was cost of production (COP) which was highest among tea producing countries where profitability is less compared to the other tea producing counterparts in the world (Ministry of Plantation Industries, 2013). Since Sri Lankan tea industry is highly export driven where over 90% of the produce is exported. Growth of NGO movements and consumer campaigns in developed countries where tea is imported are demanding for statutory, regulatory, social and environmental responsibilities throughout the supply chain starting from the plucking of green leaf to the end user

(SustainabiliTea, 2008).

Thus standard's environment has transformed in recent years (Humphrey and Memodovic, 2006) where standards can be classified broadly into private and public standards, but the line separating them is not always well defined or clear. In many instances, standards adopted by governments have their origins in the private sector (OECD, 2006) whereas public standards often specify minimum safety requirements, leaving the private sector to fill the gap beyond the minimum (Henson and Reardon, 2005). The role of private standards has been growing in importance since the 1990s (Garcia–Martinez and Poole, 2004), where exporters from developing countries must not only meet regulations of importing countries but also satisfy a plethora of private standards (OECD, 2006; Henson and Reardon, 2005). Even though the private or public standard become prominent in industry, all these standards are basically depend on HACCP for assuring food safety.

On top of that, current context of food factory concepts which needs to comply with basic hygienic requirements while certifying for voluntary certification systems such as HACCP, ISO 22000, ISO 9001, ISO 14001 and mandatory regulations such as SLTB (Sri Lanka Tea Board) monitoring measures has to be met (SustainabiliTea, 2008). These standards provides guidelines for organizations to establish their quality systems by focusing on procedures, control, and documentation (Sun et al., 2004), while conceptualizing that certain minimum characteristics of a quality management system could be usefully standardized, giving mutual benefit to suppliers and customers, and focusing on process rather than product/service quality (Van der Wiele et al., 2005). Considering the customer focus as one of the key area of customers' needs and expectations, one of the most important customer expectations in their list is to have safe food products, where ISO 9001 allows an organization to integrate its quality management system with the implementation of a food safety system (Aggelogiannopoulos et al., 2007).

Food safety was primarily regulated since mid1800s but it was mostly the responsibility of the local or state regulations in US at the time (FDA, 2004). The good manufacturing practices (GMP) were a result of requirement for consumer protection which is a set of regulations issued by authority of the Federal Food, Drug and Cosmetic Act. In 1903 the Poison Squad started raising awareness on need for food safety lead by Harvey W. Wiley, a chemist working in USDA. In 1906, Upton Sinclair published "The Jungle", a graphic exposure of the meat packing industry which was lead to pass "Pure Food and Drug Act of 1906" (Mastery Institute). The 1906 law prevented interstate and foreign commerce in misbranded or adulterated foods, drinks, or drugs. The intent of the Act was to prevent poisoning and consumer fraud (Barendsz, 1998). There were many tragedies occurred afterwards which lead to further strengthen and extend the regulations by passing The Federal Food, Drug and Cosmetic Act in 1938 (FDA, 2004). However, the GMP regulations for food processing facilities were finally proposed in 1968 and three broad categories of interrelated issues arose during the development of the GMPs (Dunkelberger, 1995). The GMP regulations were finalized in April of 1969 and published as Part 128 of the Code of Federal Regulations (CFR). In 1977, Part 128 was recodified and published as Part 110 of the CFR (Damman, 1999).

According to the General Principles of Food Hygiene of Codex Alimentarius (2003), International food trades, and foreign travel, are increasing, bringing important social and economic benefits. But it also makes the spread of illness around the world easier. there are number of quality assurance systems are available such as GMP, HACCP, ISO 9001, ISO 22000 and the international technical standard of British Retail Consortium (BRC). These systems and their combinations are applied for assuring food quality (Surak and John, 2008). On the other hand, GMP consists of fundamental principles, procedures and means needed to design a suitable environment for the production of food of acceptable quality (Frost, 2008). The basic aim of the GMP codes is to combine procedures for manufacturing and quality control in such a way that products are manufactured consistently to a quality appropriate to their intended use (DeMan and John, 1999). Nevertheless, regulatory requirements for a well-designed GMP program vary by the type of product being manufactured and by the position of the product in the manufacturing process as well as supply chain where it is important for all food manufacturers to understand

the appropriate GMP for their individual products (SPI, 2012).

A properly designed GMP system must have an appropriate infrastructure or "quality system", encompassing the organizational structure, procedures, processes and resources. It also needs to have systematic actions necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality (WHO, 2006). Nevertheless, human factor is one of most important criteria in GMP, where employee hygiene is paramount to plant sanitation and it is one of the leading causes of food contamination (Higgins, 2002). In addition, manufacturers are legally liable to take necessary measures and precautions for disease control, personnel cleanliness, supervision, education and training to comply with GMP (www.unido.org). Based on these principles, GMPs are being applied to maintain the certainty of safety in the final product where it claims for the minimum sanitary and processing requirements to ensure the production of wholesome food.

Thus General Principles of Food Hygiene is considered as the most common and comprehensive GMP document and applied to food manufacturing organizations across the globe, whereas the Section 32, Food Act, No. 26 of 1980 Sri Lanka is also have the same features. The main sections of the general principles of food hygiene has considered for:

I. Organization and Management Responsibilities;

II. Establishment, Design and Facilities;

III. Storage Facilities;

IV. Distribution Facilities;

V. Cleaning;

VI. Pest Control System;

VII. Personal Hygiene;

VIII. Quality Assurance System (Food Act, 2011);

Based on the appropriate hygiene management of above subsectors of the production process, management has to perform periodical internal as well as third party audits or inspections to validate the application of GMP (WHO, 2014). Nonetheless, training of the personnel in every step of the line is important and the management must have goal for their product, which must start from the purchase of the material and continue through processing and distribution. This goal must be well understood by the every single personnel of the establishment, because GMP is a continuous process and any negligence in one of the steps will result with an inadequate and unsafe food product (www.unido.org).

However total food safety is achieved through combination of GMP, HACCP and ISO 9001:2008 which is normally called ISO 22000:2005 (Lokunarangoadge et al., 2015). Conversely, HACCP is the most sought after food safety assuring tool which must be embedded to any food safety management system to be considered for food safety accreditations by the third party accreditors today. The Hazard Analysis Critical Control Points (HACCP) system was first invented for NASA with collaboration of Pillsbury Corporation and US Army due to the risk involved in supplying preserved food for astronauts (FAO, 1998) and it is a common sense approach in identifying, quantifying and controlling food safety hazards. Thus HACCP allow food manufacturer to carry out a detailed examination of a process to identify hazards and where the hazards can be controlled by setting up a framework (Khandke and Mayes, 1997) which is a food safety management strategy that has been widely tested and established as an effective means of preventing food-borne diseases when correctly implemented (WHO, 1993). HACCP has been designed in a way that it can be considered as a scientific and systematic system to assure food safety (Nguyen et al., 2004), while applying throughout the whole food chain (Domenech, 2008; Loc, 2006). Nevertheless, HACCP system is a proven, cost-effective method of maximizing food safety, where it

focuses on hazard control at its source which consists of seven principles of international acceptance that outline how to establish, implement and maintain an HACCP plan for an operation under the consideration (Marnellos and Tsotras, 1999). On the other hand, most of the countries had made responsible food manufactures to oblige by legislation to apply HACCP, while other systems are applied voluntarily in the food industry.

In addition, FDA has emphasized the role of prerequisite programs (PRPs) to be played while implementation of HACCP (Griffith, 2000) where it has been recommended to apply prerequisite programs before the HACCP plan is utilized, (Seward, 2000) which guarantees the assurances of GMP. Besides, HACCP complements the total quality management because it offers continuous problem prevention (Varzakas and Arvanitoyannis, 2008). Accordingly, companies have the option of adaptation to a food quality/food safety management system while communicating it to consumers, thereby gain marketing advantage and competitive advantages in the consumer level (Cao et al., 2004).

Hence, the purpose of the following study was to identify and assess the major food safety violations related to low grown orthodox black tea manufacturing industry with its sources and circumstances. Thus tea manufacturing process was considered step by step to evaluate the food safety violations which were given below.

Tea is a product with different colour, taste, smell as well as different shapes in visual appearance based on its type or variety, but its processing methods are almost similar with minor variations. The following steps are used to manufacture orthodox black tea.

Tea Plucking – First process step of the tea manufacturing is tea plucking, where tea leaves and flushes including terminal bud with two top young leaves are picked from tea (camellia sinensis) plantations and it was transported to manufacturing facilities in ventilated trucks under loosely packed conditions (Sen et al, 1983). The plucked tea leaves are subjected to leaf count at the receiving where B – 60 or "Randhalu" method is applied and if the receiving green leaves had more than 75% – 80% of tender shoots with two young leaves and bud will ensure the better quality of the final product (Wijerathne, 2008).

Withering – The first stage of black tea manufacturing is withering, which refers to the changes in green tea leaf from the time it is detached from the plant to the time of maceration (Owuor and Orchard, 1989), while chemical withering involves biochemical changes, which solely depend on time (Das, 2006). The leaves were loosely stacked in withering troughs for controlled withering with free flow of air as well as electric fans which can provide heated air flows under controlled conditions where frequent turning and mixing with supervision are mandatory. Normally withering requires 16 to 18 hours depending on the weather condition and the moisture content of the tea leaves (Samaraweera and Mohamed, 2008).

Disruption/Rolling – Most of the Sri Lankan tea factories manufacture orthodox tea which was basically carryout using orthodox or rotorvane orthodox rollers (Samaraweera and Mohamed, 2008). The disruption which is also called as leaf maceration by westerners is carryout to bruise or torn the tea leaves for the promotion of quick oxidation (Guang, 2007) which is very important in tea manufacturing process and it was carried out using manual means or mechanical means based on the requirements. The leaves are rolled by applying mechanical pressure to break up the cells and extract the cell sap at the orthodox roller with approximately around 20 minutes, the macerated leaves; still damp from the sap are sieved on roll breakers to separate the finer leaves which is called the first dhool (Samaraweera and Mohamed, 2008).

Oxidation/Fermentation – The oxidation of tea represents a series of complex chemical reactions which begins just after the cell maceration in orthodox roller where mixing up of enzymes with other chemical compounds within the cell generates number of reactions (Roberts, 2008). The oxidation process in tea manufacturing is also referred as fermentation where chlorophyll pigments in the tea leaves are enzymatically broken down while releasing the tannins or transforming into other compounds (Roberts, 1958).

Firing – The next step of orthodox tea processing was drying which is carried out to terminate biological

reactions by heat denaturation of enzymes while reducing the moisture content to increase the shelf life of orthodox black tea and to enhance the chemical reactions that are responsible for the character and flavour of orthodox black tea (Mauskar, 2007). On the other hand, firing further influence balancing of flavour of the tea, because firing eliminates some of the less desirable low boiling point compound such as volatile constituents while retaining more useful high boiling point compounds (Roberts, 2008).

Grading – The sifting is carried out by sorting the leaf particles into different sizes defending on the market demand as well as buyer requirements according to their popular blended brands. The primary objective of the sorting is to enhance the value while imparting the quality. The process of sorting enhances the appearance of the liquor quality while removing the fiber or flakes of coarse leaf particles. Thus sorting is carried out in four stages which are cleaning of fiber, grading, winnowing and colour sorting (Samaraweera and Mohamed, 2008). Nevertheless, orthodox black tea generally has four scales for quality where whole leaf tea is considered highest quality followed by broken leaves, fannings and dusts.

Bulking – The bulking of made tea is basically carryout to even the latter dhool particles as well as early dhool particles which is very important to eliminate day-to-day variations in the produce and to increase the quantity of a single grade. Most of the orthodox manufacturers use manual methods due to the small quantities manufactured with large array of grades (Samaraweera and Mohamed, 2008).

Packing – Tea is packed in paper sacks in current manufacturing facilities. Tea may be consumed after many months of preparation where it needs preservation techniques to improve the keeping quality while preserving its desirable characters which will be deteriorate due to the absorption of moisture where packing needs special attention to resistance against moisture absorption (Samaraweera and Mohamed, 2008).

Tea Brewing – Tea has to be brewed to get the liquor out where about one teaspoon or 2.25 grams of orthodox black tea is used per 180ml of water in 6 ounce cup where it must be steeped in freshly boiled water and whole leaf black teas need to be steeped around 4 to 5 minutes. But broken leaf grades require less brewing times because they have more surface area than whole leaf grades (Embole, 2011).

Further objective of the research was to assess the effectiveness of the application of HACCP based FSMS in the Sri Lankan tea processing industry and its impact as well as contribution to changing food safety assurance in Sri Lanka. The findings were used to develop an ISO 22000:2005 generic model which integrates solutions identified based on the gaps identified during the evaluations.

2 Materials and Methods

The study was designed to evaluate the major food safety violations in tea supply chain with a special attention to tea manufacturing process. Current food safety applications, their efficiency and constraints to implement proper food safety management systems as well as impact of HACCP based FSMS to improve GMP implementation and food safety in tea industry with reliable solutions while minimizing or eliminating the existing complications was the main objective of the study. The sampling plan was stratified random sampling, with the use of Factory Information.xls provided by the Sri Lanka Tea Board. The excel sheet contained contact information and addresses of the tea factories which was used to select tea factories from the low grown orthodox black tea manufacturing industries based on whether they had a food safety certification or not and then 30 factories from each group. Then selected factories were contacted and visited and persuaded for participating in the evaluation and if they agreed they were used in the analysis. The following areas were selected due to the easy access as well as shorter distances between factories where concentration of factories was high. The most prominent area was the Southern province due to the fact that low grown orthodox black tea manufacturing was prominent throughout the province while Galle, Matara and Rathnapura districts were set as major target areas for the project execution.

The project had two phases for execution. Sample size for each phase was 30 factories. The cumulative target was to evaluate 60 low grown orthodox black tea manufacturers where phase II was focused on the factories which have ISO 22000/ISO 9001/HACCP systems or Good Manufacturing Practices with Japanese 5S implementations.

However, there were number of tea factories which had been abandoned the implemented food safety management systems due to various reasons, where additional priority was given to understand the problems they faced, that led to abandoning as well as to find out the remaining practices and their efficacy.

In-depth site analyses were conducted for 45 factories out of selected 60 factories due to the rejection of site visits from some of the selected factories. The factories agreed on the site visits were evaluated based on the visual observations, documentary evidences, in-depth structured interviews and unstructured discussions. Stage I gap analysis was based on GMP compliance at the time of evaluation, while stage II internal audits were focus on the compliance of GMP with HACCP or ISO 22000 system requirements. The unstructured interviews were mostly used to gain additional insights of the organizations and their role in the industry as well as anecdotal information about real food safety practices. All the factories were evaluated against GMP since it is the basic level of registering a food manufacturing facility in the country as stipulated by the Food Act of Sri Lanka (1983). The compliance to GMP was weighted averaged to consider the real impact each and every component of the GMP can provide to the basic food hygiene to be met by food manufacturers.

The impact of HACCP based FSMS in improving food safety assurance was evaluated based on the representative sample data. The data was obtained against the GMP requirements where qualitative data was weighted averaged to convert in to quantitative values which can be used in the statistical analyses. Since the values were assigned based on the observations, there might have errors due to personal views. Thus descriptive statistics and basic statistics were used for the evaluations.

Descriptive statistics defining the food safety and GMP achievement levels in the different areas under consideration were segregated, while computing and comparing the mean/median and standard deviation of Organization and Management Responsibilities (O&MR), Establishment Design and Facilities (ED&F), Storage Facilities (SF), Distribution Facilities (DF), Cleaning, Pest Control System (PCS), Personal Hygiene (PH) and Quality Assurance System (QAS) with the particular attention in case the company has a valid ISO 9000 or HACCP certificate. The evaluation carried out using gap analysis and ISO 22000 internal audit document.

For comparing multiple variables, descriptive statistics, Spearman Rho, Box Plot and Pie Charts were used, depending on the requirements. Data transformations were performed as necessary. The Nonparametric Mann-Whitney test was performed as explained below to find out; if there was any significant relationship to the improvement of food safety assurance due to the implementation of HACCP based FSMS in tea industry.

The descriptive statistics

The summary of descriptive statistics provide the bird-eye view of the data set with results of basic statistics which represents Descriptive statistics, Anderson-Darling Normality Test statistics with Confidence intervals for μ, σ, and the median. Nevertheless, 95% confidence intervals for μ, and 95% confidence intervals for the median where it analyze each column or variable represent in the data table. Thus graphical summary was applied for the data set and the results were used to interpret individual results of each component tested against GMP. Thus results provide answers to the data distribution. In addition, the 8 areas were individually tested for evaluation of impact of implementation of HACCP based FSMS in tea industry using nonparametric Mann-Whitney test.

Spearman rank-order correlation (Spearman's rho)

The obtained data was evaluated using descriptive statistics to find out correlation between various components tested and their relationship strength. The objective was achieved through Spearman rank-correlation test. The Spearman correlation coefficient is based on the ranked values for each variable rather than the raw data. Thus Spearman correlation was used to evaluate relationships involving ordinal variables which were to be evaluated to find out correlations among sections under GMP requirements.

The data was checked to display p-values for the hypothesis test where;

H_0 = There is no monotonic correlation present in population

H_1 = There is a monotonic correlation present in the population

The data was analyzed under the 5% significance level for decision making.

The box plot

The Box plot was used to understand the overall pattern of the responses for two groups which visualized the range and other characteristics specific for individual data sets. The total scores achieved by the sample were segregated in two groups depending on the availability of a HACCP based FSMS or not. The factories had HACCP was assigned with 1 while factories without HACCP was assigned with 0.

Nonparametric Mann-Whitney test

The sample population was tested using nonparametric Mann-Whitney test to determine whether two populations have the same population median (η); where nonparametric Mann-Whitney test was used to compare the two samples to tests the null hypothesis that the two population medians.

H_0 (Null Hypothesis): $\eta 0 \geqq \eta 1$

H_1 (Alternative Hypothesis): $\eta 0 < \eta 1$

The data was analyzed under the 5% significance level for decision making.

The alternative hypothesis can be left-tailed ($\eta 0 < \eta 1$), right-tailed ($\eta 0 > \eta 1$), or two-tailed ($\eta_1 \neq \eta_2$). The Mann-Whitney test uses the ranks of the sample data, instead of their specific values, to detect statistical significance. In addition, Mann-Whitney test does not require the data to be normally distributed populations, but it does needs to comply with the following assumptions:

The populations of interest have the same shape

The populations are independent

H_0 = There is no significant impact on implementation of HACCP based FSMS to improve food safety assurance in tea industry and;

H_1 = There is a significant impact on implementation of HACCP based FSMS to improve food safety assurance in tea industry.

The obtained data were tested using Minitab 17 Version, where results were obtained using standard test procedures given in the basic statistics.

The food safety violations based on GMP requirements and their achievements were evaluated using the collected data. In-depth site analysis was carried as discussed above where visual observations, documentary evidences, in-depth structured interviews and unstructured discussions were conducted. The food safety violation and major contributors to the gaps in food safety was evaluated using Pareto principle, after conducting the gap analysis for designed sample; the major areas for the interventions needed were decided based on Pareto analysis where 20% of the root causes were responsible for the 80% of the problems. The food safety compliances and non-compliances were compared using Pie Chart.

3 Results and Discussion

The effectiveness of the application of HACCP based FSMS in assuring food safety, has been proven in many industries around the world, where HACCP improves business performance (Khatri and Collin, 2007; Taylor, 2001; Romano et al., 2004), operational performance (Khatri and Collin, 2007) and overall quality performance (Trienkens and Zuurbier, 2008). Thus research was intended to find out the areas already implemented and their effectiveness and impact to improve the food safety as well as areas to be improved in the Sri Lankan tea industry and contribution to changing food safety assurance in Sri Lanka. The food safety violations of the given industry were observed as to the methodology and qualitative data was converted in to quantitative values using weighed averages. The obtained values were evaluated using descriptive statistics to derive validated explanations. Since

the collected data was designed to evaluate gaps in the GMP requirements, following results were obtained.

Table 1 Descriptive Statistics - O&MR, ED&F, SF, DF, Cleaning, PCS, PH, QAS, Total

Variable	Mean	StDev	Minimum	Median	Maximum
O&MR	6.767	1.394	4.000	7.000	9.000
ED&F	17.767	4.247	11.000	18.000	25.000
SF	5.140	1.754	3.000	5.000	9.000
DF	5.930	1.298	4.000	6.000	8.000
Cleaning	3.047	0.722	2.000	3.000	4.000
PCS	2.442	0.666	2.000	2.000	4.000
PH	3.326	0.919	2.000	3.000	6.000
QAS	11.884	2.666	6.000	12.000	16.000
Total	56.72	11.87	39.00	56.00	78.00

The summary statistics showed as above (Table 1) Mean, Median, Standard Deviation, Minimum and Maximum values for each variable or the areas segregated according to the importance of GMP requirements and the weightages given considering the impact on food safety. Based on the above results, tea factories have implemented GMP with a total median of 56 where minimum and maximum values varied in between 39~78 within the sample. In addition, Spearman Rho was tested and it (as to the below Table 2) provided relevant P-values which further explains the correlations between different components of testing criteria.

Table 2 Spearman Rho - O&MR, ED&F, SF, DF, Cleaning, PCS, PH, QAS, Total

	O&MR	ED&F	SF	DF	Cleaning	PCS	PH	QAS
ED&F	0.794							
	0.000							
SF	0.692	0.775						
	0.000	0.000						
DF	0.522	0.592	0.769					
	0.000	0.000	0.000					
Cleaning	0.584	0.570	0.582	0.419				
	0.000	0.000	0.000	0.005				
PCS	0.482	0.415	0.268	0.071	0.539			
	0.001	0.006	0.082	0.653	0.000			
PH	0.615	0.627	0.503	0.465	0.405	0.124		
	0.000	0.000	0.001	0.002	0.007	0.429		
QAS	0.735	0.788	0.726	0.639	0.731	0.494	0.508	
	0.000	0.000	0.000	0.000	0.000	0.001	0.001	
Total	0.853	0.929	0.874	0.736	0.704	0.469	0.654	0.912
	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

Note: Cell contents: Spearman rho, P-Value

The Spearman's rank correlation coefficient or Spearman's rho was conducted in order to determine if there were any relationships between the 8 different areas (O&MR, ED&F, SF, DF, Cleaning, PCS, PH, QAS,) of the GMP; based on the values assigned. A two-tailed test of significance indicated that there were significant positive relationship between the organization and management responsibility (O&MR), establishment design and facilities (ED&F) and this was the strongest correlation among tested components. Nevertheless, it further shows that the most insignificant or weakest relationships can be observed among distribution facilities (DF) and personal hygiene (PH) with pest control systems (PCS). On the other hand, quality assurance systems had stronger or moderate relationship with all the other components tested, where better the quality assurance system; better their good manufacturing practices (GMP) and same pattern can be observed in O&MR. All un-circled results were showed moderate relationships between tested components.

The comparison of tea factories with and without HACCP system was carried out using boxplot graph and descriptive statistics combined with nonparametric Mann-Whitney test. The following Figure 1 shows the impact of HACCP based FSMS with higher levels of GMP and food safety achievement between the two groups due to the implementation of HACCP. Considering the group of factories used for evaluation, the G_0 (Factories without HACCP) group has lower median value (47) with short whisker (39) for the lower side and longer whisker for upper side (64) with an outlier (78). In contrast, factories implemented HACCP based FSMS (G_1 - Factories with HACCP) had a higher median value (66.5) with the upper whisker, which is short (77) and lower whisker is long (47). The data set spread with left skewed pattern in HACCP implemented factories while G_0 had a right skewed pattern of data showing that there was significant difference between two groups based on the availability of HACCP based FSMS or not, which further confirms that; HACCP based FSMSs such as HACCP improve the business performance (Khatri and Collin, 2007; Taylor, 2001; Romano et al., 2004) and it is also true with ISO 22000 (Bilalis et al., 2009).

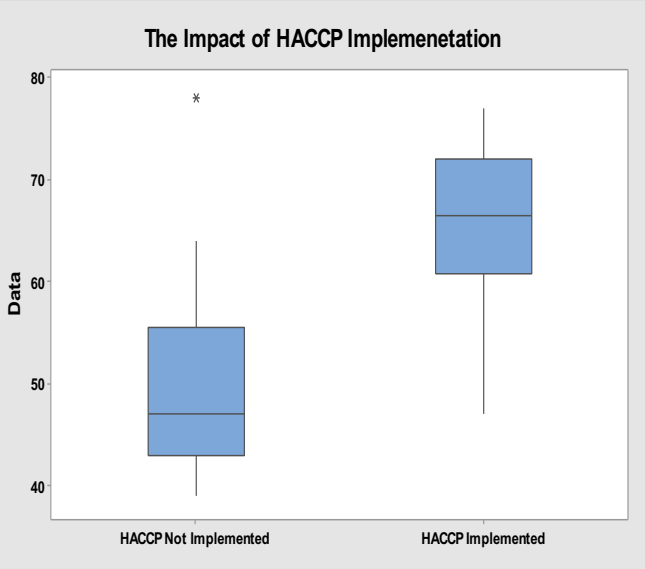

Figure 1 Impact of HACCP based FSMS in Sri Lankan Tea Industry

Thus data were further analyzed using descriptive statistics and nonparametric Mann-Whitney tests for the evaluation of impact and the areas of impacts. Minitab 17 was used to calculate the sample medians of the collected data of gap analysis and internal audits based on the implementation of HACCP based FSMS. The resulting medians are given in the Table 3, the table further shows the relevant W and P-values related to each component tested under GMP requirements (OM&R, ED&F, SF, DF, Cleaning, PCS, PH, QAS) as well as the overall results for impact of HACCP implementation (Total). Considering the overall achievements due to the implementation of HACCP based FSMS, the medians were 47.00 and 66.50, where there was a 95.2% confidence interval for the difference in population medians (HACCP Not Implemented - HACCP Implemented) is [-22.003 to -10.997]. The test statistic W = 376.5 has a p-value of 0.0000 and 0.0000 when adjusted for ties. Since the p-value is less than the chosen α level of 0.05, there is sufficient evidence to reject H_0. Thus, the data supports the hypothesis that there is a difference between the population medians and it further conclude that; implementation of HACCP based FSMS has a positive impact of improving food safety assurance in Sri Lankan tea industry whereas Implementation of QAS are improving operational efficiency and reduce the production costs (Henson and Holt, 2000; Turner et al., 2000; Madonadon-Siman et al., 2009) and being recognized as employing "best practice", or a "good system", with new technology and innovation (Henson and Holt, 2000; Deohar, 2003; Jayasinghe and Henson, 2004; Mandonado-Siman et al., 2009).

In contrast, Table 3 further shows that, there is no any significant relationship between HACCP based FSMS implemented factories and not implemented factories on cleaning (P-value 0.074) and pest control systems (P-value 0.619) where chosen α level was higher than the 0.05. The visual observations made on the field also tally with this result, because both category of factories had similar levels of cleaning with insufficient documentations and very low level of pest control system implementations where Table 3 shows (Red colour circles) insignificant difference at 95% confidence level. Other P-values shows (blue colour circles) that HACCP based FSMS implementation has helped the tea industry to efficiently implement GMP compliances while improving the organizational management and responsibility, establishment design and facilities, storage facilities, distribution facilities, personnel hygiene and quality assurance systems at 95% confidence interval.

Table 3 Impact of implementation of HACCP based FSMS on food safety assurance in Sri Lankan tea industry

Descriptive Statistics							ND Mann-Whitney	
Variable	HACCP	Mean	StDev	Minimum	Median	Maximum	W	P-Value
O&MR	0	6.160	1.281	4.000	6.000	9.000	414.0	0.0004
	1	7.611	1.092	5.000	8.000	9.000		
ED&F	0	15.280	3.273	11.000	15.000	25.000	369.0	0.0000
	1	21.222	2.777	15.000	22.000	24.000		
SF	0	4.440	1.557	3.000	4.000	9.000	424.0	0.0010
	1	6.111	1.568	3.000	6.000	8.000		
DF	0	5.480	1.262	4.000	5.000	8.000	441.0	0.0380
	1	6.556	1.097	5.000	7.000	8.000		
Cleaning	0	2.800	0.645	2.000	3.000	4.000	450.5	0.0740
	1	3.389	0.698	2.000	3.500	4.000		
PCS	0	2.280	0.542	2. 000	2.000	4.000	487.0	0.6190
	1	2.667	0.767	2.000	2.500	4.000		
PH	0	3.120	1.013	2.000	3.000	6.000	465.0	0.0188
	1	3.611	0.698	3.000	3.500	5.000		
QAS	0	10.360	2.177	6.000	10.000	15.000	371.5	0.0000
	1	14.000	1.645	10.000	14.000	16.000		
Total	0	49.92	9.35	39.00	47.00	78.00	376.5	0.0000
	1	65.17	7.90	47.00	66.50	77.00		

Note: 0 - HACCP Based FSMS Not Implemented, 1 - HACCP Based FSMS Implemented

Organization and Management Responsibility

According to the Table 1, general population of factories was half way through O&MR achievements. The achievements can be varied within minimum and maximum values 04 - 09 with a median in between 6.0 - 7.0 at 95% confidence level. In addition, the P-value and W (0.0004, 414) for nonparametric Mann-Whitney test further justify the alternative hypothesis, which was implementation of HACCP based FSMS has positively impacted (Table 3) on tea industry in improving GMP implementation and there by food safety of the final product; due to top management's support and influence on adoption of QASs (Thompson, 1965; Daft and Becker, 1978).

Establishment Design and Facilities

The Establishment Design and Facilities had a great impact on the entire food safety of the facility as well as all the components tested on GMP. The summary statistics shows 95% confidence interval (Table 1) for minimum of 11 and maximum of 25 and mean value of 17.79 for the sample which can be used as an indication of the achievements in GMP implementation. This further explains the improvements required. The P-vale, 0.0000 and W, 369 where difference between mean values were 15.280 and 21.222 (Table 3) for the nonparametric Mann-Whitney test which further explains the positive impact of implementation of HACCP based FSMS in tea industry.

Storage Facilities

According to the Table 1, the study sample showed mean of 4.59 to 5.67 and median of 4 - 6 under 95% confidence interval (CI) which further explain the improvements needed due to the high number of 3 and 4 scores achieved out of 10, as to the results obtained. When compared the factories with and without HACCP based FSMS, mean was 4.44 for factories without HACCP and 6.11 for factories with HACCP based FSMS, where W - 424 and P-value - 0.001 (Table 3) which shows the relationship between implementation of HACCP based FSMS and its positive impact generated in tea industry.

Distribution Facilities

As to the results, most of the tea factories involved in the evaluation has achieved 5 or more than 5 marks and according to the curve it is right shifted with a median of 6 and mean of 5.93 where the industry has better

distribution and collection facilities generally under a 95% confidence level. Nevertheless, DF has moderately positive relationship (Table 3) where W 441 and P-value was 0.0380 which still rejects the null hypothesis while proving that, HACCP based FSMS implementation had improved distribution facilities of the tea industry at a 95% CI. DF has a strong correlation with storage facilities while it has no relationship with PC according to the Table 3, whereas it further showed a moderately high relationship with QAS concluding that distribution facilities are moderately improved than other areas of tea industry.

Cleaning

Out of the 5 marks given most of the factories have achieved 3 marks as to the results. The median was 3 where mean value also changed within a very narrow range. The minimum and maximum was changed in-between 2 - 4; which shows that, tea industry needs to improve their cleaning operation as a whole. According to the Spearman's rho, the cleaning has a stronger relationship with QAS (Table 3), but it further showed that there was no any significant improvements in cleaning whether factory has implemented a HACCP based FSMS or not. This was the visual observation too, since tea industry need to focus on its cleaning activities because cleaning was very inadequate in many places without making any impact due to the implementation of HACCP based FSMS.

Pest Control Systems

As to the results, most of the tea factories achieved 2 points out of 5 which shows very low levels of achievements in tea industry. Accordingly, mean varies between 2.0 - 2.3 under 95% confidence interval, where minimum and maximum varies between 2 - 4. In addition, PCS has no relationship with SF (P, 0.082) or DF (P, 0.653) according to Table 2, while it has very weak relationship with PH. Furthermore, PCS showed null hypothesis was true where HACCP based FSMS has not made any differences to the improvement of GMP through improving PCS. Thus tea industry has to focus on improving PCS for the betterment of food safety.

Personal Hygiene

The statistical summary (Table 1) on personnel hygiene also shows the very lower achievements by concentrating the mean value of 3.3 which was far below the average value. Since minimum and maximum values were 2 to 6, the achievements in the general factory population also show the same pattern at 95% confidence. In line with the Spearman rho (Table 2), PH has moderate relationships with all the components evaluated other than PCS which was discussed previously. However, PH has accepted alternative hypothesis (W, 465 and P, 0.0188) where it was positively correlated, but as to the mean and the median PH achievements were very low for both HACCP based FSMS implemented tea factories as well as not implemented. Thus tea industry has to consider improving its operators PH for the betterment of consumer safety.

Quality Assurance Systems

According to the Table 1, it shows the results of quality assurance systems (QAS) implementation of the sample evaluated. Based on the above statistical outputs, it is obvious that industry needs a shift in quality assurance system implementation. Quality assurance systems had improved the operational performance (Khatri and Collins, 2007) with food safety and quality of product manufactured (Trienekens and Zuurbier, 2008) while improving the infrastructure which intern had increased the points scored by individual factories who has implemented HACCP based FSMS. Out of given 20 points, the result has varied between minimum of 6 to maximum of 16 where mean value has shifted only from 11.0 to 12.7 proving that QAS has more works to be done in the tea industry. As to the Spearman rho, QAS has strong relationship with O&MR, ED&F, SF and Cleaning while it has moderate relationships with all other areas under consideration. All the P-values were much less than 0.05 proving that the alternative hypothesis was acceptable. Besides, mean value and median (Table 3) had considerable difference between factories with HACCP based FSMS and without. It also showed a positive correlation while accepting the alternative hypothesis where HACCP based FSMS implementation in tea industry has created an enabling environment to improve the GMP conditions as well as food safety in tea industry. In addition, 5S implementation has further help to systematize and improve the effectiveness of implementation of GMP where most of the factories which has implemented HACCP based FSMS has implemented 5S before they implemented FSMS. The

efficiency of processing, recording and personnel hygiene were satisfactorily improved in factories who have implemented HACCP based FSMS and 5S, where improving product quality is an important motivation to adopt HACCP by firms in the agri-food sector (Deodhar, 2003; Jin et al., 2008). The Japanese 5S has played a major role in improving infrastructure and training of workers where visual implementations were highly concerned. Nevertheless, factories with HACCP based FSMS has better infrastructure and systematic operations with trained operators rather than factories without any HACCP based FSMS, because food producers adopt HACCP in order to satisfy downstream customers in the food chain (Mazzoco, 1996; Henson et al., 1999).

Food safety violations in low grown orthodox black tea manufacturing industry were further evaluated using Pareto analysis which was based on 20:80 principle and pie chart. After the gap analysis, the collected information was used to find out major issues related to food safety violations and the generic documentation system development was initiated to fill the gaps in documentation. The relevant requirements were carefully defined according to the documentation requirements stated in ISO 22000:2005. In addition, ISO 30300:2011 was considered for the development of record management system while merging 5S into the ISO 22000:2005 within the area of work instructions, cleaning and preventive maintenance (Lokunarangodage et al., 2015). The tea industry was carefully analyzed with reference to the operating environment and the type of documents needed for the relevant processes compatible with ISO 22000:2005 FSMS to ensure the proper management of the food safety.

After conducting the gap analysis for the industry sector; the major areas for the interventions needed were decided based on Pareto principle where 20% of the root causes were responsible for the 80% of the problems which was shown in Figure 2 below. Thus study was planned to address most critical issues of the industry with regards to the food safety violations and the food safety assurance. According to the Pareto chart (Figure 2), it was obvious that Establishment Design and Facilities was the major root cause for the food hygiene problems identified where continuous attention and Top Management commitment as well as additional capital investments were needed to improve design and facilities of the manufacturing plants in the sector. On the other hand, next major contribution for food safety violation was found in the area of Quality Assurance Systems (Figure 2), where none of the existing systems were in compliance with complete food safety. However, firms strive to maintain or improve both safety and quality attributes together and such efforts are closely interrelated and most likely are managed as the whole in practice (Herath et al., 2007). This was mostly due to the incomplete system developments, lack of expert knowledge in the industry and also due to the inappropriate practices.

Nonetheless, Personnel Hygiene also contributed to food safety violations because employee training was very rare and it was neglected even among the organizations having ISO 22000 certifications, where worker knowledge on this area was highly unsatisfactory. Evidences showed that conducted training programs were also not up to the standards and basically concentrated on very few areas of the requirements. Storage Facilities became the next contender, which was a part of Establishment Design and Facilities because if these facilities were adequately developed storage facilities were also developed according to the requirements. Furthermore, the fermentation area was identified as another major point in food safety violations where food hygiene was very vulnerable and ignored by many manufacturers including factories with HACCP based FSMSs. The gap was bridged by designing a fermentation trolley with specific features.

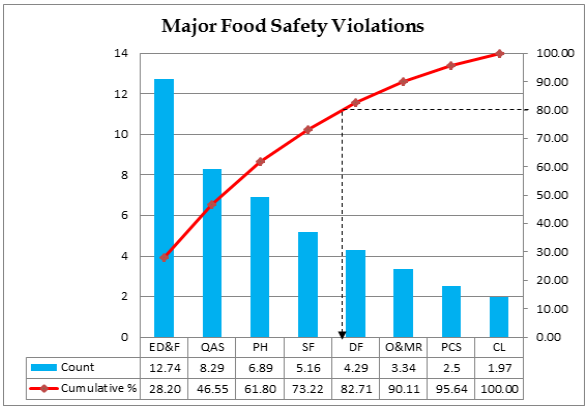

Figure 2 Contribution of food safety violations from evaluated sectors

Even through Organization and Management Responsibility, Distribution Facilities and Cleaning was out of the 80% of Pareto Chart (Figure 2) management responsibility was one of the major requirements because, if the management committed to improve the factory condition all these problems were eliminated. Thus there was a direct relationship between all other factors with Organization and Management Responsibility and it was a proportional relationship which is also true for the quality assurance systems. Cleaning can be improved with proper training and organizing workers in to area specific teams under the proper guidance of the management.

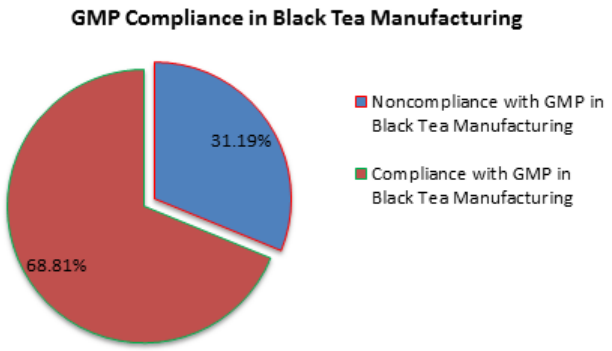

Figure 3 Comparison of Good Manufacturing Practices compliances and noncompliances

According to the above evaluations, ISO 22000 requirements were further analyzed to develop a generic model while absorbing existing practices into the generic model which can help tea manufactures with more convenient manner, since the manufacturing process is more or less similar with all orthodox black tea manufacturing facilities. The initiative was based on the allowances made by the ISO 22000:2005 which specifically states "this international standard allows an organization (such as a small and/or less developed organization) to implement an externally developed combination of control measures" (ISO 22000:2005, 2005) which was further stressed by the official guide book by ISO and the ITC "ISO 22000 - Are you ready?" where ISO 22000:2005 permits an organization to choose between developing its own control measures or using one developed by an industry association, government agency, university etc. (Chambers, 2007).

Above pie chart (Figure 3) shows the average compliance levels achieved in the area of GMP based on the reference sample, which further explain the 31.19% of GMP deficiencies that must be improved before planning an ISO 22000:2005 food safety management system. The generic model was a customizable food safety system based on ISO 22000:2005, which can be readjusted according to the factory specific requirements where very few thing to be changed before implementation. The advantage was that, quality officers working in tea manufacturing facilities will be able to modify the system according to factory requirements for the initiation of the system and they also can conduct internal training programs based on the given presentations. If they have the opportunity to participate for externally conducted internal auditing programs, then they can ready the system for initial auditing, at the first stage audit or mock audit by the certification service provider will request for any additional specific requirement based on the specific manufacturing process. Auditor may even tell them what exactly is the compliance criteria to be met before certification, this will help the industry to implement their own systems where ownership of the system belong to the factory officer and he will motivate to implement and run the system while learning it, rather than getting consultancies from someone don't know exactly about the industry. Thus generic model was designed with above objectives where it contains all the mandatory documents which were described in ISO 22000:2005 standard.

4 Conclusions

Thus HACCP based food safety systems have created enabling environment to improve GMP requirements in the industry which has increased the food safety implementation in tea industry. Nevertheless, factories with HACCP based FSMS has better infrastructure and systematic operations with trained operators rather than factories without any HACCP based FSMS. The efficiency of processing, recording and personnel hygiene were satisfactorily improved in factories who have implemented HACCP and 5S. The Japanese 5S has played a major role in improving infrastructure and training of workers where visual implementations were highly concerned.

Establishment Design and Facilities was the major root cause for the food hygiene problems identified in tea

manufacturing process where continuous attention and Top Management commitment as well as additional capital investments were required to improve design and facilities of the manufacturing plants in the sector. Quality Assurance Systems were the next contributor to the lack of food safety in orthodox black tea manufacturing process, where none of the existing systems were in compliance with complete food safety. This was mostly due to the incomplete system developments, lack of expert knowledge in the industry and also due to the inappropriate practices. Nonetheless, Personnel Hygiene also contributed to food safety violations because employee training was very rare and it was neglected even among the organizations having ISO 22000 certifications, where worker knowledge on this area was highly unsatisfactory.

Furthermore, the fermentation area was identified as one of the major points in food safety violations where food hygiene was very vulnerable and ignored by many manufacturers including factories with HACCP based FSMSs.

Thus there was a direct relationship between all other factors with Organization and Management Responsibility and it was a proportional relationship which was also true for quality assurance systems. Cleaning can be improved with proper training and organizing workers in to area specific teams under the proper guidance of the management.

A generic model was designed based on the requirements of ISO 22000:2005 to bridge the gaps identified in orthodox black tea manufacturing process which can be customizable according to the specific manufacturing requirements with slight changes.

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