Assessment of Prerequisite Programs Implementation and Hygiene Status at Food Packaging Companies in Mount Lebanon: Cross-Sectional Study

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List of Abbreviations

USA: United States of America

ISO: International Organization for Standardization

HACCP: Hazard Analysis of Critical Control Points

CFU: Colony Forming Units

PVC: Polyvinyl chloride

PE: Polyethylene

Spp.: Species

uc: Uncountable

MPN: Most Probable Number

CCPs: Critical Control Points

PRPs: Prerequisite Programs

BRC: British Retail Consortium

FSSC: Food Safety System Certification

TS: Technical Specification

FSMA: Food Safety Modernization Act

FDA: Food and Drug Authority

EC: European Commission

EU: European Union

NL EN: Lebanese Conformity English

LIBNOR: Lebanese Standards Institution

GMP: Good Manufacturing Practices

FSMS: Food Safety Management System

MA: Mesophilic aerobes

GHP: Good Hygiene Practices

RTE: Ready To Eat

CN: Cellulose Nitrate

IRI: Industrial Research Institute

ANSI: American National Standards Institute

ANAB: ANSI National Accreditation Board

ilac-MRA: International Laboratory Accreditation Cooperation Mutual Recognition Arrangement

TVC: Total Viable Count

AOAC: Association of Official Analytical Chemists

TSA: Tryptic Soy Agar

VRBG: Violet Red Bile Glucose Agar

SDA :Sabouraud Dextrose Agar

SD: Standard Deviation

QMS Quality Management System

COVID-19: Corona Virus Disease of 2019

DL: Detection Limit

Abstract

Food packaging has a critical role in all food types and along the food chain from product preservation to transportation, distribution, storage, retailing, and end-use. However, it can become a source of contamination and transfer of microorganisms to the packed food when its hygienic status is not well maintained. The aim of this study was to evaluate the Prerequisite programs (PRPs) implementation in 5 food packaging companies across Mount Lebanon through on-site inspections and to assess the compliance of contact surfaces, employee hands and packaging materials to microbiological specifications. Following on-site inspection, none of the companies achieved a full total score of 100% and scores ranged from 25 to 62%. Regarding the assessment of hygienic status of contact surfaces, non-conforming results (acceptable limit $\leq$ 0.6 log CFU/cm^2) were observed in 50% (5/10) of the surfaces for total viable count (TVC). For the employee hands, none of the hand swab samples (10/10) was conforming for TVC that was present in all samples above the acceptable limit. Highest and lowest reported values were 4.4 and 1.7 log CFU/hands respectively. For packaging samples collected during on-site inspections, TVC and yeasts and molds were detected in 20% (2/10) of the samples but the counts were within the acceptable limit. As for the samples collected from the retail market, TVC was detected 95% (19/20) of samples but the counts didn't exceed the set acceptable limit. Yeasts and molds were detected within acceptable limit in 65% (13/20) of the samples with the highest value in a dairy/ice cream sample at 1.1 log CFU/Container. As for *Enterobacteriaceae,* it not detected in all tested contact surfaces, employees' hands and packaging samples. PRPs assessment and related verification

activities showed the need for companies to strengthen their hygienic programs and highlighted the importance of food safety management systems implementation not only in food companies but also in food packaging companies. Additionally, the effectiveness of PRPs implementation should be assessed on planned routine basis.

Key Words**:** on-site inspection; food packaging; packaging contamination; acceptance criteria; contact surface; hand swabs

Chapter 1

1. Introduction

Food packaging is defined as a coordinated system of preparing food for transport, distribution, storage, retailing, and end-use (Shin and Selke, 2014). One of the major purposes of food packaging, i.e. the protection of foods against microbiological contamination and microbial stability during shelf-life, may not be ensured if the paperboard material is contaminated (Delgado *et al.*, 2012). Microbial risks associated with packaging surfaces or during its manufacturing stage are often overlooked because of the perception that microorganisms cannot survive in plastic materials (Zaman *et al.*,2018).Traditionally, paper and packaging manufacturers have not necessarily considered safety and hygiene requirements as such an important factor as is considered in the food industry, but as more emphasis is placed on food safety and hygiene, an awareness of the critical role of packaging is increasing (Raaska, 2005).

Therefore, an important focus should be set on the prevention of microbial entrance portals along the entire supply chain to avoid even low microbiological contamination levels of the food packaging material (Feichtinger *et al.*, 2015). The importance of hygiene in the paper and packaging industry has increased considerably as a result of more specific demands in legislation, tighter international competition, and increasing customer requirements (Raaska, 2005). As important raw material suppliers for the food industry, manufacturers of packaging materials are expected to bring their standard hygiene in line with the expectations of the food industry (Raaska, 2005).

2. Contamination of food packaging material with microorganisms

It is commonly thought that food packaging material seem as inert materials that cannot harbor any living organisms; however, studies conducted on them showed contamination. Paper manufacturing is an open process, and the raw materials (e.g., wood, straw, starch, mineral pigments) contain bacteria, and thus, the products are not free of microorganisms (Ekman *et al.*, 2009). Food packaging material is at risk for microbiological and fungal contamination (Suihko and Stackebrandt, 2003).Even though the heat treatment (80–128^{o}C) and drying at the end of the papermaking process improve the microbiological quality of the final paper product (Suihko and Skyttä,1997), these operations are not sufficient to eliminate bacterial spores occurring in the pulp (Suihko and Skyttä,1997); they inactivate fungi and vegetative bacteria whereas heat resistant bacterial spores not only survive but may become activated (Pirttijärvi,2000). *Bacilli* commonly found in food packaging boards were found to possess one or several of the following properties potentially relating to food spoilage: food degrading enzyme activities, growth at a refrigerated temperature or at ≥ 50°C and tolerance to a wide range of pH (Pirttijärvi,2000).

In Iran, a study was carried out on food grade cling film since no clear criteria or standards have been released about the microbial community of Cling films (Mirzaei *et al.*,2016). Fifteen samples of food grade cling film were purchased from supermarkets in Iran originating from various countries including Canada, Germany, Iran, Korea, Poland and USA (Mirzaei *et al.*,2016). Samples were intended to be tested for the isolation and characterization of dominant species found on them (Mirzaei *et al.*,2016). For the experimental section, one meter of the sample's length was discarded in order to avoid

contamination, then one gram of each sample was used for standard plate count for total microorganisms (Mirzaei *et al.*,2016). Experiments were carried out in triplicate, then identification of bacteria isolates from samples was carried out. No fungus contamination was observed in all samples, possibly ascribed to the belief that chemicals and heat used during paperboard production are more in effect against fungi than bacterial spores (Mirzaei *et al.*,2016). According to dilution series result, four samples had uncountable colonies and bacterial contaminations from other four samples were counted (Table 1) (Mirzaei *et al.*,2016). One of five Iranian samples had bacterial contamination, one of the Korean samples which had uncountable colonies contained two different contaminations, and sample from Germany had the highest bacterial contamination (Mirzaei *et al.*,2016). As per the study in order to reduce the spread of contaminated material, an international limit and testing at particular control points for quality control should be done for international trade (Mirzaei *et al.*,2016).

In another study conducted in Poland, the microbiological infection of various paper and paperboard materials for uses in contact with food were assessed (Guzińska *et al.*, 2012). Assessment was done by three different methods; which were compared to select the best suited one. The three methods were: defibering method, agar flooding method, and smear method. Samples were obtained from producers of packaging and acquired on the market. Testing by the agar flooding method only permitted to approximately assess the contamination level due to the mutual over-flooding of the colonies and a difficult reading of results (Guzińska *et al.*, 2012). The smear method is not suited to the estimation of bacteria and fungi number in samples of paper and paperboard (Guzińska *et*

al., 2012). The defibering method according to standard ISO 8784-1:2005 is best suited to the testing of microbiological purity of paper and paperboard intended for contact with food (Guzińska *et al.*, 2012). The method enables a precise estimation of bacteria and fungi number in both very pure and highly contaminated samples (Guzińska *et al.*, 2012). Results of defibering method are detailed in Table 1; however, they were not compared against any limits for acceptance criteria. Polish standard which stipulates health standards of paperboard and paper packaging for food does not set microbiological demands; it only included organoleptic features and content of heavy metals only (Guzińska *et al.*, 2012). Their study showed that results of contamination were low for paper and high in paper board due to its non-compact fibrous composite structure (Guzińska *et al.*, 2012). In addition, a criterion for microbiological purity of paper and paperboard intended for packaging material should be established (Guzińska *et al.*, 2012).

A similar study was conducted in Iran to determine the bioburden and type of contaminated bacteria in the current food packaging paperboard and to compare the same three methods (Mashhadi *et al.*,2015). The only difference from the Polish study is that biochemical tests were carried out to determine the type of bacteria found and fungus was not tested. Samples were obtained from famous fast food restaurant and confectionary in Tehran city (Mashhadi *et al.*,2015). The defibiring method was also chosen as the best suited method and bacterial identification was done based on its results (Mashhadi *et al.*,2015). All samples were contaminated with bacteria (Mashhadi *et al.*,2015). The most common detected bacteria were found to be the family *Bacillaceae* that *Bacillus licheniformis* and the *Bacillus subtilis* were showed the maximum and minimum number

of bacteria, respectively (Mashhadi *et al.*,2015). The lowest number of bacteria was found on parchment paper and the highest belong to fried chicken and cookie boxes (Table 1) (Mashhadi *et al.*,2015). The study showed that HACCP for food packaging industries and measures to decrease contamination of packaging materials made out of paper and paper board is urged (Mashhadi *et al.*,2015).

A recent study in relevance to the above, was conducted in India to gain knowledge on the bacteria present in food papers and paper boards with various contents of pulp fiber (Sood and Sharma, 2019). Samples were obtained from local nearby markets of Saharanpur,India (Sood and Sharma, 2019). Results showed that from the 10 tested food packaging paper boards, bacteria were present in all the samples (Table 1) (Sood and Sharma, 2019). Defibiring method was the only method used, then isolation of pure colonies by streak plate method was conducted followed by biochemical tests (Sood and Sharma, 2019). Out of 10 samples which were tested, three samples were contaminated with *Bacilleus subtilis*, four samples with *Bacilleus cereus,* two samples with *Staphylococcus aureus* and one sample with *Pseudomonas aeroginisa* (Sood and Sharma, 2019). *Bacillus* genera form heat-resistant spores which describe its survival during the drying phase of paper board machine operation (Sood and Sharma, 2019). In accordance to the Polish study (Guzińska *et al.*, 2012) and Iranian study (Mashhadi *et al.*,2015), results also show that the number of microbes that were estimated in paperboard are much higher than in paper (Sood and Sharma, 2019). The source of bacteria *Bacillus* and *Pseudomonas* has been identified in agro-residues present in the raw material (Sood and Sharma, 2019). The study showed that bacteria present in the Indian food paper and paper

boards may cause health hazards and cause the potential risk of rejection of food packages due to odorous compounds generation, which are catalyzed by enzymes produced by bacteria (Sood and Sharma, 2019).

A study in Brazil aimed at enumerating and identifying molds (heat labile and heat resistant) on the surface of paperboard material used for aseptic filling (Delgado *et al.*, 2012). Another aim of the study was selecting the isolates with the highest resistance to heat and hydrogen peroxide and determining inactivation kinetics of the most resistant isolate for commercial filling of tomato pulp (Delgado *et al.*, 2012). The study mentioned that even though laminated paperboards are sterilized before use with a combination of heat and hydrogen peroxide; the occurrence of unusual high populations of molds due to failures during storage of packaging materials or the existence of molds presenting an exceptional heat and chemical resistance should be taken into account (Delgado *et al.*, 2012). A total of 68 samples of laminated paperboard were collected from two plants A and B before the hydrogen peroxide bath and filling (Delgado *et al.*, 2012). This was done before package formation by rubbing the paperboard material inner surface (polyethylene) with sterile cellulose sponges during operation of machines (Delgado *et al.*, 2012). Enumeration of heat-labile and heat-resistant molds was performed (Delgado *et al.*, 2012). From the seven isolates, two (*Paecilomyces variotii* F1A1 and *Tessaracoccus flavus* F5E2) were found in counts varying from 0.71 to 0.35 CFU/100 cm^2 and 1 CFU/100 cm^2, respectively, which may represent a challenge for packaging sterilization as these species have been shown to present a high chemical and heat resistance (Delgado *et al.*, 2012). In the same manner a total of 50 samples of unfilled but

formed packages were collected after the hydrogen peroxide bath (Delgado *et al.*, 2012). Then survey of cardboard layer for mold contamination was conducted by taking the cardboard layer of 20 packages from 4 different lots (n = 5 packages/lot) (Delgado *et al.*, 2012). The collected packages were opened under aseptic conditions and tomato pulps were discharged (Delgado *et al.*, 2012). Analyses of the laminated paperboard material after the hydrogen peroxide bath and of the cardboard layer of the laminated paperboard material have shown no contamination by molds (Delgado *et al.*, 2012). However, from the prepared suspension of spores, results showed, *Paecilomyces variotii* survived heating (while *Tessaracoccus flavus* showed less resistance) at 85^{o}C/15 min and, taking into consideration its resistance to hydrogen peroxide, this mold might be capable of surviving packaging sterilization (Delgado *et al.*, 2012).

Finally, a study in Helsinki aimed to identify the bacteria contaminating food packaging board and to characterize their properties relevant to food spoilage and food safety by isolation and enumeration of bacteria in homogenate paperboard standard on inner surface of carton packages (Pirttijärvi, 2000). Results showed food packaging paper and board contained as contaminants mainly spore forming bacteria belonging to the genera *Bacillus, Paenibacillus* and *Brevibacillus* (Pirttijärvi,2000). However, the contaminants were found in quantities from <50 to 250 CFU/g homogenized paperboard, which are lower than in many foods (Pirttijärvi,2000).

3. Transfer of microorganisms from packaging material to food

While some studies show that the microbial load is usually low and may be limited to bacterial endospores or fungal spores (Feichtinger *et al.*, 2015), however the effect of this contamination is also relative to the food product stored in it. Food products with high water activity and high density of nutrients have a relevant risk of contamination (Feichtinger *et al.*, 2015). When favorable factors are present and contaminated food packaging material comes in contact with food for sufficient time, risk of bacterial proliferation is increased. Following the above studies showing contamination of primary packaging in contact with food; the below studies examined the transfer of contamination to food.

In Egypt, the effect of packaging container (plastic and cardboard) on the bacteriological profile of Egyptian soft cheese at plant level was studied (Ibrahim and Sobeih, 2010). Ninety random samples of soft cheese and their containers were collected from dairy plants; soft cheese samples were collected just before and after plastic container packaging and cardboard laminated packaging (Ibrahim and Sobeih, 2010). Also, 30 samples of the plastic containers and the cardboard laminated sheets (15 of each) were included (Table 1) (Ibrahim and Sobeih, 2010). Results showed a significant positive relationship between the level of soft cheese contamination (especially with aerobic plate count, aerobic spore-formers and *Staphylococci*) as a result of their packaging in plastic containers and cardboard laminated containers (Ibrahim and Sobeih, 2010). In contrast, Coliforms and *Enterococci* counts had non-significant correlation with package containers of cheese (Ibrahim and Sobeih, 2010). The increase was explained by the

possibility of a certain permeability of the packaging used (Ibrahim and Sobeih, 2010). The study showed that packaging material used for heat-treated milk should be free from pathogenic bacteria and also from other microorganisms that may multiply in the milk or product under favorable conditions (Ibrahim and Sobeih, 2010). Packaging materials were shown to be a significant source of cheese contamination as microorganisms can grow rapidly on food surface, especially the dairy products and also during sealing of the packages (Ibrahim and Sobeih, 2010).

Table 1 Food packaging material sampling methods

Type of Food Packaging Tested & Sample Size	**Method**	**Results**				**Criteria**	**Reference**
Food quality Cling films (PVC & PE) (N=15)	1g of film serial dilution and plating	**Pathogen**	**CFU**	**Polymer**	**Sample**	<250 bacterial CFU/g	(Mirzaei *et al.*,2016)
		Bacillus Spp.	Uncountable (uc)	PVC	Canada		
		Bacillus Spp.	uc	PVC	Poland		
		Bacillus Spp.	uc	PVC	USA	<500 colonies of mesophilic aerobic bacteria (Iranian National Standards)	
		Staph. Aureus & Bacillus Spp.	uc	PVC	Korea		
		Bacillus Spp.	$3.2x10^3$	PE	Canada		
		Bacillus Spp.	$1.6x10^4$	PE	Iran		
		Staph. aureus	$5x10^4$	PE	Canada		
		Klebsiella Spp.	$3 x 10^2$	PVC	Korea		

<table>
<tr><td rowspan="9">Paper (N=3) &

Paper Board (N=5)</td><td rowspan="9">Defibering Method according to ISO 8784.

*Mean results are shown

(The number of the microorganisms was calculated per 1 g of tested sample, per dry mass of the paper, and per 100 cm^2 of the paper)</td><td>Sample</td><td>Bacteria number. u/g</td><td>Fungi number u/g</td><td>Dry Mass %</td><td rowspan="9">Not Defined</td><td rowspan="9">(Guzińska et al.,2012)</td></tr>
<tr><td>Paper wrapping for soft candies</td><td>1.0×10^2</td><td>$<1.0\times10^1$</td><td>96</td></tr>
<tr><td>Pad for box of confectionary</td><td>5.4×10^2</td><td>$<1.1\times10^1$</td><td>93.6</td></tr>
<tr><td>Paper bag for dry material sugar</td><td>1.2×10^3</td><td>2.0×10^1</td><td>96</td></tr>
<tr><td>Board box for confectionary (1)</td><td>7.4×10^5</td><td>$<1.1\times10^1$</td><td>92.8</td></tr>
<tr><td>Board box for confectionary (2)</td><td>5.3×10^5</td><td>$<1.1\times10^1$</td><td>92.6</td></tr>
<tr><td>packaging paperboard (1)</td><td>4.4×10^6</td><td>2.6×10^3</td><td>93.6</td></tr>
<tr><td>packaging paperboard (2)</td><td>4.4×10^6</td><td>4.3×10^1</td><td>93.6</td></tr>
<tr><td>Paperboard packaging for pizza</td><td>6.5×10^6</td><td>4.4×10^2</td><td>91.9</td></tr>
<tr><td rowspan="3">Paper (N=3) &

Paper Board (N=12)</td><td rowspan="3">Defibering Method (ISO 8784)</td><td colspan="2">Sample</td><td colspan="2">Bacteria CFU/g</td><td rowspan="3">Not Defined</td><td rowspan="3">(Mashhadi et al.,2015)</td></tr>
<tr><td rowspan="2">Pizza Box

(A=1st sample=</td><td>A</td><td colspan="2">4.08×10^3</td></tr>
<tr><td>B</td><td colspan="2">0.96×10^3</td></tr>
</table>

		2nd sample, C= 3rd sample)	C	17.0×10^3		
		Parchment Paper	A	0.33×10^3		
			B	0.397×10^3		
			C	0.2×10^3		
		Cookie Box	A	$>1.0\times10^5$		
			B	6.15×10^3		
			C	2.115×10^3		
		French Fries Box	A	21.74×10^3		
			B	8.35×10^3		
			C	1.6×10^3		
		Fried Chicken Box	A	$>1.0\times10^5$		
			B	15.3×10^3		
			C	7.55×10^3		
Paper & Paper Board (N=10)	Defibering Method (ISO 8784) *Mean results are shown	**Sample**		**Number of Bacteria (CFU/g)**	<250 bacterial CFU/g	(Sood & Sharma, 2019)
		Paper plate		6.7×10^2		
		Cake box		8.7×10^2		
		Fruit tray		6.1×10^3		
		Tissue paper		1.3×10^2		
		Coffee cup		3.2×10^2		
		Pastry box		6.9×10^2		
		Sweet box		7.6×10^2		
		Pizza box		9.8×10^2		

		French fries box		7.2×10^2		
		Paper bag		4.8×10^2		
Plastic containers (500g capacity) (N=15) and cardboard laminated sheets (N=15) intended for cheese packaging	Plastic container was rinsed with 20 ml of sterile buffer solution /Cardboard laminated sheets: Swab method *Mean results are shown	**Bacterial counts**	**Plastic containers (CFU/package)** Mean ± S.E	**Cardboard laminated packages (CFU/ cm^2)** Mean ± S.E	< 50 CFU/package of more than 100 ml capacity	(Ibrahim & Sobeih, 2010)
		Aerobic plate count (APC)	4.49 X 10^3 ± 0.91X 10^3	1.17 X 10^3 ± 0.20 X10^3	< 1CFU/cm of product contact surface in case of laminated cardboard sheet	
		Aerobic sporeformer count	1.83 X 10^2 ± 0.35 X 10^2	4.40 X 10 ± 0.79 X10		
		Coliform count (MPN)	6.14 X 10 ± 1.27 X10	2.33 X 10 ± 0.42 X 10	Free of coliform	
		***Staphylococci* count**	3.92 X 10^2 ± 0.74 x 10^2	2.94 X 10^2 ± 0.61 X 10^2		
		Enterococci count	2.33 x 10^2 ± 0.56 x 10^2	1.33 X 10^2 ± 0.25 X 10^2		

Another study aimed to explore the microbial transfer dynamics from packaging to packed peaches in relation to the packaging used (Patrignani *et al.*,2016). A challenge test was performed by inoculating *Escherichiacoli*, *Pseudomonas* spp. and *Saccharomyces cerevisia*e on cardboards and reusable plastic containers, and monitoring their cell loads on fruits according to a probabilistic model and a Response Surface Methodology in relation to several independent variables (number of fruit lesions, fruit temperature storage and commercialization time) (Patrignani *et al.*,2016). The quality of 30 peaches

was evaluated, after sanitizing and before packaging (Patrignani *et al.*,2016). All levels of *Pseudomonas* spp., yeasts and *E.coli* were under the detection limits (Patrignani *et al.*,2016). The data showed a higher contamination frequency of the fruits packed in plastic than in cardboard (Patrignani *et al.*,2016). Increasing the storage temperature and the number of lesions, the probability of transferring of *Escherichia coli* from packaging materials to fruits increased, independently on commercialization time or packaging used (Patrignani *et al.*,2016). For *Pseudomonas*, the contamination levels detected on fruits packaged in plastic were significantly higher compared to those found on fruits packed in cardboard, independently on the considered variables (Patrignani *et al.*,2016). The study showed that an important strategy to increase food safety can be by choosing the right type of material for reduction of transferring of the microorganisms (Patrignani *et al.*,2016).

4. Potential sources of contamination

Different types of food packaging material have different processing methods, and are exposed to different risk factors that were considered as microbiological CCPs in HACCP plans developed for the production of food packaging material (Sjöberg *et al.*,2002).Different PRPs included: type of circulation water, starch used for surface sizing, use of lacquers or glues, process environment: working practices and birds and insects, storage of fiber raw materials, reused pallets, and end products in intermediate storage, and storage of end products (Sjöberg *et al.*,2002). In addition, the routes of contamination from the package to food include the surface, cutting dust or direct contact to the raw edge of the paperboard (Pirttijärvi,2000). All of these steps may introduce passage ways for bacterial contamination if left uncontrolled because of growth of

potential pathogenic microbes and contamination of microbes, long storage times, anaerobic conditions, biofilm formation, and unsuitable working practices (Sjöberg *et al.*,2002).

Continuous surveillance and good manufacturing practice are the best techniques for prevention of contamination (Mirzaei *et al.*,2016); such as dust-prevention or tight sealing in polyethylene bags can heavily reduce microbial contamination rates of packaging material (Tacker *et al.*,2002). Effective cleaning and preservation techniques and good manufacturing practices are required in these processes to maintain high hygienic quality in the end product (Pirttijärvi,2000). Moreover, to enhance the health and product quality during manufacturing food packages, the equipment, hands of employees and air should go under microbial examination (Mashhadi *et al.*, 2015).

5. Standards for food packaging material manufacturing

Due to the importance of adhering to proper PRPs in food packaging production; there exist standards for food safety systems' enforcement in food packaging companies. These standards include but are not limited to: BRC Global Standard for packaging and packaging material, FSSC 22000 which is ISO 22000:2005 standard in conjunction with technical specification on the prerequisite programs (PRPs) on food safety ISO/TS 22002-4 and other specific requirements for each country for e.g. US Department of Health and Human Services pasteurized milk ordinance, Food and Drug Authority's Food Safety Modernization Act (FSMA) in the USA, (EC) No. 1935/2004 of the European Union in EU member countries, NL EN 13427:2007 and NL EN 15593:2012 of LIBNOR in Lebanon. These standards are put in place in order to ensure that the risk of any

contamination (physical, chemical, or biological) is mitigated to the least possible occurrence. Even though these standards are available there is no baseline information on the extent of adherence to these standards by Lebanese food packaging companies.

6. Assessment of the status of hygiene requirements in manufacturing facilities

6.1 PRP evaluation

PRPs assessment is based on the evaluation of: establishment layout and workspace, utilities, waste disposal, equipment suitability, cleaning and maintenance, management of purchased materials and services, measures for prevention of contamination, cleaning, pest control, personnel hygiene and facilities, rework, withdrawal procedures, storage and transport, food packaging information and customer communication, food defense and bioterrorism (ISO/TS 22002-4:2013).In order to asses PRP requirements in several industries, different checklists can be audited against using different scoring systems (Table 2).

Table 2. Different scoring methods to evaluate PRPs

Criteria Assessed	Type of Industry	Country	Sample Size	Scoring	Objective Measurement	Reference
HACCP/PRPs questionnaire	Public school foodservice	Portugal	N=88	Yes/No Checklist	Temperatures of food, refrigerators, and freezers	(Liz Martins and Rocha, 2014)

HACCP/PRPs questionnaire	Private catering services (schools, geriatric centers, business companies, and hospital)	Spain	N=15	Yes/No Checklist	-Food sampling and microbial analyses -Surfaces sampling and microbial analyses -Food handlers sampling and microbial analyses	(Garayoa *et al.*, 2016)
HACCP /PRP questionnaire	Food businesses	Turkey	N=109	Scoring grid: full compliance (3-point), minor deficiency (2-point), major deficiency (1-point) and non-compliance (0-point).	Temperatures of food, refrigerators, freezers, and dish washing machines	(Bas *et al.*, 2006)
HACCP/PRPs questionnaire	Chain restaurants	Iran	N=58	5-point Likert rating scale: 1-5 (1: no compliance, 5: full compliance).	N/A	(Tavakkoli *et al.*, 2015)
GMP, HACCP, PRP questionnaire	Government and private hospitals	Turkey	N=20	4-point Likert scale: full compliance (3 points) ,(2 points) minor deficiency , (1 point) major deficiency; and (0 points) noncompliance	N/A	(Bas *et al.*, 2005)
GMP checklist	Mozzarella cheese processing unit	Brazil	N=1	-"conformity" (when the requisite was fully adhered), -"non-conformity" (when the requisite was partially adhered or not adhered) -"not applicable" was assigned	N/A	(Costa Dias *et al.*, 2012)
FSMS assessment checklist	Animal-based food production	Europe (Belgium, Netherlands, Greece,	N=100	Scoring grid :a low (score 0), basic (score 1), average (score	N/A	(Luning *et al.*,2015)

	companies	Italy, and Spain)		2), and advanced (score 3)		
GMP/GHP & HACCP Audit	Children's nurseries foodservice	Warsaw	N=55	Grading scale: highest score 5= all the requirements being met (100% compliance); lowest score 2= only a minority of the requirements were fulfilled (less than 40% compliance).	N/A	(Trafialek *et al.*,2019)

6.2 Objective measurements

Verification activities are performed in order to assure effective PRP are put in place as the best techniques for prevention of contamination. These activities are often objective measurements that include microbiological testing for verification of e.g. personnel hygiene, cleaning practices, and end-product safety. Testing programs that include both samples from environmental verification sites as well as finished product samples are increasingly recognized as an effective approach to validate and/or verify food safety systems (Simmons and Wiedmann, 2018).Different objective measurements can include: food contact surface testing (Table 3), employee hand testing (Table 3), packaging material testing (Table 1).

Table 3. Hand and food contact surfaces sampling methods

Objective	Sampling Method of Food Contact Surface	Sampling Method of Hands	Pathogens Tested	Reference
Evaluation of the microbial risk associated in bulk food bags manufacturing facilities in each step of production according to hazard analysis	Swab samples: production floors, machine surfaces, sewing machines, and floors surfaces	Swab samples from operator's open hand & gloves. When gloves were collected, they were aseptically poured into sterile plastic zip lock bags containing sterile saline	• Total aerobic bacteria • Total coliform bacteria • Total fecal coliform count • *Escherichia coli* • *Streptococcus* spp. • Fecal *Streptococcus* spp. • *Staphylococcus* spp. • *Salmonella* spp.	(Zaman *et al.*,2018).
Evaluation of the microbiological contamination on food-contact utensils and handlers'-contact utensils	Petrifilm™ count plates circular gel portion of the top film was put in direct contact with utensils in contact with food handlers (10 types) and utensils in contact with food (21 types)	Petrifilm™ count plates circular gel portion of the top film was put in direct contact with both hands during food preparation.	• Mesophilic bacteria (food contact surfaces) • *Enterobacteriaceae* (both) • *E. coli* (hands) • *Staphylococcus aureus.* (hands)	(Valero *et al.*, 2017)
Verification tools to support observational data (HACCP/PRPs questionnaire results)	Flat surfaces were tested using Rodac contact plates containing Plate Count Agar in each kitchen, classified as food-contact surfaces or hand contact surfaces	Swab samples (swab rinse technique were taken from both hands (bare or gloved if they carried gloves while handling food), before and after the usual hand wash procedure.	• Mesophilic aerobes (MA) • *Enterobacteriaceae* • *Staphylococcus* spp. (hand swabs only)	(Garayoa *et al.*, 2016)
Evaluation of parameter of a good sanitation practice of food contact surfaces after the cleaning and sanitation procedures and parameters that can survive and contaminate food during processing or storage in food retail outlets or storage.	Samples of most used food contact surfaces in stores of the following food categories: raw meat (17 surfaces), deli (11), pastry (18), fishery products (12) and dairy products (10) (after sanitation)	N/A	• Total aerobic count • *Salmonella* spp. • *Listeria monocytogenes*	(Losito *et al.*, 2017)
Evaluation of the effectiveness of FSMS on high school kitchens	Swabs of 10 different kitchen surfaces (including spoons, forks, knifes, soup		• Mesophilic aerobic bacterial count	(Illés *et al.*,2018)

by characterizing the microbial profile of food contact surfaces	plates, dinner plates, dessert plates, kitchen tables, serving utensils, catering trays, and drinking glasses)	N/A

6.3 Assessment of food safety management systems and PRPs in different foodservice and processing facilities

For catering services located in northern Spain; characterization was that none achieved the maximum score (43), with total scores ranging from 19 to 36 points (Garayoa *et al.*, 2016). In 60.0% of the kitchens, the PRPs were not completely implemented; the most important deviations were the lack of a maintenance plan for facilities and equipment (40.0%) and the insufficient storage space for foods (60.0%) (Garayoa *et al.*, 2016). Repeated deviations were the following: lack of specific sinks for hand washing (73.3%); not enough storage capacity in warehouses, cold rooms and freezers (60.0% of the kitchens); food products in contact with the soil (40.0%); poor stock rotation (66.7%); and finally, absence of dustbins with pedal (40.0%) in the preparation and cooking areas (Garayoa *et al.*, 2016). Food handlers testing showed that mesophilic aerobic microorganisms were present in 91.3% of the food workers' hands, while *Staphylococcus* spp. and *Enterobacteriacea*e were detected less frequently (53.3% and 22.8%, respectively) (Garayoa *et al.*, 2016). For surface testing, 86.7% and 96.7% of food contact surfaces were conforming to the mesophilic aerobes and *Enterobacteriaceae* criteria, respectively, showing good cleaning and disinfection standards (Garayoa *et al.*, 2016). No significant differences were found between work and distribution utensils (Garayoa *et al.*, 2016). Higher counts of mesophilic aerobes and *Enterobacteriaceae* were related to lower total checklist scores (Garayoa *et al.*, 2016).

In food businesses, out of 109 facilities assessed in Turkey for HACCP-PRPs and food safety practices; only eight food businesses had implemented the HACCP system (Bas *et al.*, 2006). Directors and employees often had insufficient knowledge regarding the basics of food hygiene and results indicated that proper food safety practices and PRPs for HACCP were often not being followed in many food businesses (Bas *et al.*, 2006). Time and temperature errors and inadequate handwashing practices were wide in the most food businesses (Bas *et al.*, 2006). The problems of implementing HACCP in food businesses have been namely a low level of food hygiene management training, high staff turnover rate, lack of motivation, lack of financial resources, inadequate equipment and physical conditions of the facility and failure of government (Bas *et al.*, 2006).

A different study for the same author conducted on government and private hospitals evaluation in Ankara, Turkey showed that 65.1% of food service staff had received food safety training (Bas *et al.*, 2005). Mean personal hygiene practices and operational control procedures scores on the prerequisite questionnaire were 55.3% ± 14.7% and 63.7% ± 8.6%, respectively (Bas *et al.*, 2005). The overall mean score on the prerequisite questionnaire for hospital food service was 57.5% ± 6.4% (Bas *et al.*, 2005). In addition, most hospital food services were not measuring and recording food temperatures (95.0%) (Bas *et al.*, 2005). Taking and recording endpoint temperatures of all cooked foods were implemented by 5.0% of hospital food service directors; for food temperatures taken by the survey team, the temperatures of cold foods were frequently higher than the recommended temperature (4°C) (Bas *et al.*, 2005).

In the study aimed at school foodservice characterization, results showed that proper food-handling practices were not being followed in many school foodservice operations

evaluated (Liz Martins and Rocha, 2014). Regarding food temperature control, taking and recording endpoint temperatures of all cooked foods was the most frequent nonconformity, at 60% of foodservices evaluated (Liz Martins and Rocha, 2014). In addition, lack of dedicated hand washing sink in food preparation and distribution areas with proper drying setting was observed in 60% of units (Liz Martins and Rocha, 2014). All foodservice units revealed non-conformities on cleaning and disinfection practices of equipment and facilities (Liz Martins and Rocha, 2014). In regard to facilities and equipment, incorrect handling of waste was found in all foodservices evaluated (Liz Martins and Rocha, 2014). As for storage, food storage in adequate containers and freezing and refrigeration temperature documentation were good practices found in all school foodservice evaluated (Liz Martins and Rocha, 2014). Finally, adequate facilities for meals production were found in all food units evaluated (Liz Martins and Rocha, 2014).

Great chain restaurants evaluation in Iran showed that none of the restaurants were generally in a poor status, but only 17 % of them were assessed in a proper level and had required qualifications for HACCP implementation (Tavakkoli *et al.*, 2015). 62 % of restaurants had proper area and location and 52 % of them were in a proper compliance level for environmental hygiene (waste and sewage disposal, lighting, ventilation, water infiltration and controlling programs for insects and rodents) (Tavakkoli *et al.*, 2015). None of the restaurants had adequate quality for documentation, and all had poor condition for storage, cold storage and refrigerator (Tavakkoli *et al.*, 2015).

After good manufacturing practices including PRPs were assessed in a mozzarella cheese processing plant in Brazil, results were used to formulate corrective actions.

Effectiveness of implementation was compared before and after implementation of GMP where percentage of conformity increased from 32% to 66% after GMP implementation (Costa Dias *et al.*, 2012).

The significance of effectiveness of recommendations for proper PRP planning and implementation can show tangible results on the reduction of bacterial load. This was demonstrated in a study conducted in Serbia in meat processing plants and meat retail, where hand swab acceptability (TVC $\leq$ 2.7 log CFU/cm^2), increased from 47.29-48.9 to 97-98.96 % before and after HACCP implementation, respectively (Tomasevic *et al.*,2016).

For food safety management systems in European (Belgium, Netherlands, Greece, Italy, and Spain) in animal-based food production companies, the majority of companies (84/100) showed good overall safety output scores (≥2–3) (Table 2) (Luning *et al.* 2015). Seventy-eight companies in this group operate in an overall moderate to moderate-high risk context and have systems performing minimally at average (n = 30) or more advanced levels (n = 48) (Luning *et al.* 2015). The much smaller group of companies (16/100) showed lower overall food safety output scores (≤2) (Table 2) (Luning *et al.* 2015). Results of comparing context characteristics (product and process indicators, organization indicators, and chain environment indicators) for the various sized companies shows that riskiness of product and process characteristics do not differ significantly (Luning *et al.* 2015). In the FSMS performance, it is evident that fresh products scored significantly lower on indicators related to design, actual operation, and assurance of intervention processes (Luning *et al.* 2015). For the product groups, the dairy products showed most differences in performance of FSMS activities compared to

the other products (Luning *et al.* 2015). The scores were lower for cooling, calibration, and corrective actions but higher for adequacy and capability of intervention equipment (Luning *et al.* 2015). In food safety output, all indicators related to safety and hygiene complaints and non-conformities scored lower for the fresh products (Luning *et al.* 2015).

In children's nurseries in Warsaw results showed that the level of compliance with both GMP/GHP and HACCP standards was high in respect of documentation (Trafialek *et al.*,2019). However, it was much lower in the case of practice, especially HACCP (Trafialek *et al.*,2019). Although a constant increase in compliance with HACCP criteria was observed over the evaluated period (11 years), improvement was slow and inadequate (Trafialek *et al.*,2019). The adopted scale used in the study did not contain a clearly defined center, which allowed the auditor some scope to exercise their judgement when awarding final scores during evaluation.

In evaluation of the microbiological contamination on food handlers during food preparation for collective meals in Spain, *Enterobacteriaceae* were present in 62.1% of food handlers' samples as well as *Escherichia coli* and *Staphylococcus aureus* (7.5% and 26.6%, respectively) (Valero *et al.*, 2017). 53.0% of the utensils in contact with food handlers (10 types) and utensils in contact with food (21 types) were positive for at least one of the bacterial groups studied and 328 among those (27.1%) with counts between 1 and 15 CFU/plate (Valero *et al.*,2017). Contamination routes from food handlers to handlers'-utensils was identified in a bidirectional way, being it subsequently spread to utensils in contact with foods (Valero *et al.*, 2017).

The study for evaluation of the hygienic conditions of food contact surfaces after the cleaning and sanitation procedures, in five food retail outlets located in the Apulia region,

Southern Italy showed the highest rates of improvable or not compliant data found in the stores of raw meat (38 and 29%, respectively) and fishery products (23 and 31%), followed by deli (21 and 13%) (Losito *et al.*, 2017). As no regulatory limits have been established for food contact surfaces, the compliance criteria proposed in this study could be used to monitor the cleaning and sanitation procedures in the food distribution system (Losito *et al.*, 2017). Criteria entails compliant (from not detectable to 49 CFU/cm^2), improvable (between 50 and 499 CFU/cm^2) and not compliant (>500 CFU/cm^2) (Losito *et al.*, 2017).

In the study of high school kitchens; mesophilic aerobic bacterial count values above the satisfactory limit (<2.40 log10 CFU/100 cm^2) were measured on kitchen desks, catering trays, and on soup plates (Illés *et al.*,2018). Significant differences were detected between the microbial load of the assessed kitchens. There were kitchens where the mesophilic aerobic bacterial count on all sampled surfaces was satisfactory (<2.40 log10 CFU/100 cm^2) while there were kitchens where this count was unsatisfactory (>2.40 log10 CFU/100 cm^2) in all surfaces (Illés *et al.*,2018). In connection with the unfavorable results, the food hygiene knowledge level of kitchen workers was unsatisfactory (Illés *et al.*,2018).

6.4 Assessment of food packaging hygienic status

Studies performed a basic risk assessment to evaluate the microbial and/or fungal load at set zones, steps, machines considered as sources of contamination in food packaging companies.

The first study evaluated study was the risk of microbial contamination in Flexible Intermediate Bulk Containers (known as bulk bags) manufacturing facilities intended to use for bulk food transportation, and also to evaluate a cost-effective way to minimize the microbial risk in bulk bag manufacturing facility (Zaman *et al.*,2018). A flow diagram with the steps involved in manufacturing was set and each step was evaluated for risk and tested accordingly (Zaman *et al.*,2018). Samples varied according to contact of the roll with the source of contamination e.g. employee hands, gloves, tapes, table surfaces, printing and fed machine surfaces, liner, machine surfaces, floor, utensils, sewing machine surfaces, fabric's inner/outer surfaces, air wash machine, and bailing machine inner surfaces (Zaman *et al.*,2018). Selected portions of polypropylene woven fabrics and tape were cut with sterile scissor and workers hand gloves were collected aseptically from the bulk bag manufacturing line and was poured into sterile plastic zip lock bags containing sterile saline (0.85%) solution to facilitate recovery of adhered microorganism (Zaman *et al.*,2018). Production floors, machine surfaces; operators open hand and gloves, inside surface of bulk bag liners, worker's hands, sewing machines, and floors surfaces samples were taken by swabbing (Zaman *et al.*,2018). A total 243 swab samples from 23 locations throughout the bulk bag manufacturing process were collected and analyzed (Zaman *et al.*,2018). Absence of microbial contaminations in fabrics at loom machine and the loom machine operator's hand reflect that the GMP was practiced (Zaman *et al.*,2018). The air blowing duct of liner extrusion section including air samples, inner and outer duct surfaces, was seen free of microbes as because of the periodic maintenance of air quality, filters parts, and heating system (Zaman *et al.*,2018). Presence of higher aerobic and coliform bacteria was evident in the liner inner surfaces of

the rolls, which might be due to the post processing contamination come from operator's hand while sewing the fabrics (Zaman *et al.*,2018). The highest bacterial load (3.3 log CFU/swab) was observed in the clean room floor surfaces (between sewing machine lines) compared to weaving machine surfaces and liner production area (Zaman *et al.*,2018). On the other hand, presence of *Staphylococcus* spp. (1.0 log CFU/cm^2) in the clean room surfaces suggested the inadequate sanitization of the place because *Staphylococcus* spp. is very sensitive to heat and sanitizers (Zaman *et al.*,2018). Results also showed that moderate number of total aerobic bacteria (≤3.68 log CFU/unit), coliform (≤3.63 log CFU/unit), fecal coliform (1.0–1.25 log CFU/unit), *Staphylococcus* spp. count (≤3.6 log CFU/unit) was recorded in worker's hand gloves and different sections of the whole bulk packaging production facility (Zaman *et al.*,2018). Although no *Escherichia co*li or *Salmonella* spp. was detected, enrichment culture study detected *Streptococcus* spp., and fecal *Streptococcus* spp. in some swabs and hand gloves samples (Zaman *et al.*,2018). This microbiological assessment found presence of hazard exists at three points, including (a) hand gloves were contaminated and they were reused without sanitization; (b) workers used bear hands or contaminated gloves in the finished products storage room; (c) the clean room floor surfaces were not sanitized, along the production line of bulk container bags (Zaman *et al.*,2018).

Another study conducted in Japan studied the distribution of filamentous fungi in a production line for plastic caps for soft drink bottles filled according to the aseptic method; where six rooms were identified: 5 of which are located in a closed area;1 of which could directly open out (Sato, 2010). Swab tests were conducted on the spots that were visibly recognized to be contaminated with fine plastic particles in the 6 rooms;

samples were inoculated, incubated and emerging colonies were isolated and identified to the level on genera by fungal slide culture method and by giant colony method (Sato, 2010). Secondly, air samples were obtained using air sampler with agar strips for fungi from the 6 rooms; same testing method for identification of fungal genera as swabs was used (Sato, 2010). Finally, raw materials for plastic caps including the base resin, the master batch, and the linear material were evaluated for their fungal level by Most Probable Number method; filamentous fungi genera were also identified similar to swabbing method identification (Sato, 2010). Results showed from both the swab and air sampling tests out of 52 samples; 47 filamentous fungi were isolated (Sato, 2010). 32 isolated filamentous fungi were from swab samples mostly recovered from printing/inspection room followed by resin storage room; which could be explained by employee touching the devices for printing machine adjustment (Sato, 2010). Only hyphae could be seen for 14 isolates, which is why they were not identified (Sato, 2010). As for raw materials, fungal count was zero most probable number/100g for the base resin, 0.36 most probable number/100g for the master batch, and 4.3 most probable number/100g for the linear material; identified genera were: *Penicillium*, *Trichoderma*, *Cladosporium* which were found in production area samples (Sato, 2010). The results indicate an average of 0.9 filamentous fungi per sample; showing good hygienic conditions (Sato, 2010). Whereas the 47 types of Filamentous fungi isolated can cause deformation and corrosion of plastic materials including those for the packaging of processed foods (Sato, 2010).

The third study in Finland aimed to carry out detailed quantification of microorganisms in refined paper manufacturing processes (Raaska, 2002). In addition to a quantitative

determination of different microbial groups, another goal was to identify the bacterial isolates and to create a RiboPrint identification database for these bacteria (Raaska, 2002). Microbial surveys were carried out for process surfaces (including those in storage and refining areas) by using the commercial rapid cultivation methods. For process samples (starch – based glues) and raw material paper and end products; pour-plate method from logarithmic dilutions was used (Raaska, 2002). The process surfaces were analyzed twice and process samples and end products three times (Raaska, 2002). The microbial surveys were carried out by determining total aerobic bacteria, *Enterobacteria*, yeasts and molds from 100 surface samples, and by determining aerobic bacteria, aerobic spore - forming bacteria, *Enterobacteria*, yeasts and molds from 19 glue samples, 2 raw material paper and 9 end product samples. In addition, aerobic bacteria, yeasts and molds were determined from 27 ambient air samples by sediment plates (Raaska, 2002). Raw material paper and end – product samples were taken aseptically into a sterile bag with the aid of a sterile knife (Raaska, 2002). Microbial enumeration was conducted then characterization and identification of bacterial isolates was performed (Raaska, 2002). Results verified that the production and use of pasteurized starch-based glue was the most important factor threatening the process hygiene and product safety (Raaska, 2002). Subsequently, the production and use of starch-based glue was changed, and a follow-up program targeting the microbiological quality of glue was developed as part of a hygiene and safety management system (Raaska, 2002). A total of 33 spore-forming bacterial and 15 *Entero* bacterial isolates were ribo-typed, and 22 and 10 different ribogroups, respectively, were generated (Raaska, 2002). These isolates from starch-based glue, raw material paper and end products were atypical and, thus, in many cases physiological,

chemotaxonomic and molecular results did not correspond (Raaska, 2002). The most common spore-forming bacteria (55% of the isolates) were *Paenibacillus* spp. and within this genus several new species were also proposed (Raaska, 2002). The most common *Enterobacteria* (87%) were *Enterobacter cloacae* and *Citrobacter freundii* belonging to bacteria in hazard group 2, or species closely related to them (Raaska, 2002).The paper focused on process hygiene and product safety in the production of refined paper products intended for contact with food (Raaska, 2002). The microbial surveys provided information concerning the quantity and identity of microbes evident on or in process surfaces, raw materials and final products (Raaska, 2002). The microbe determination process clearly indicated points that were not microbiologically clean (Raaska, 2002).

Several research studies were found on the evaluation of PRPs in different foodservice and food processing facilities with relevant objective testing; however while there has been much research on food packaging material microbiological load, fungal contamination, and environmental testing and efforts of testing at relevant risk introducing steps (Zaman *et al.*,2018; Raaska, 2002); there were no studies found that conducted a full PRP compliance assessment on food packaging companies in conjunction with objective verification testing.

Chapter 2

1. Introduction

Food packaging is defined as a coordinated system of preparing food for transport, distribution, storage, retailing, and end-use (Shin and Selke, 2014). The main role of packaging is to hold, protect and preserve food product integrity against potential damage from climatic, microbiological and transit hazards (Ayoub *et al.,* 2018). However, the packaging itself can become a source of food contamination when its hygienic status is not well maintained. Previous studies showed that packaging material such as paper and paper boards were contaminated by high bacterial counts and yeasts and molds (Guzińska *et al.,* 2012; Mashhadi *et al.,* 2015; Sood and Sharma, 2019); in addition to contamination of cling film by *Bacillus* spp., *Staphylococcus* aureus, *Klebsiella* spp. (Mirzaei *et al.,* 2016). After packaging soft cheese in plastic container and cardboard laminated sheets; counts in cheese increased for aerobic plate count, aerobic spore-formers, coliforms, Staphylococci, Enterococci (Ibrahim and Sobeih, 2010). In addition, inoculated reusable plastic containers and cardboard contaminated packed peaches with *Escherichia coli, Pseudomonas,* and *Saccharomyces cerevisiae* (Patrignani *et al.,* 2016). When contaminated packaging is in direct contact with food, it can transfer spoilage microorganisms and/or pathogens to the product causing quality deterioration, food waste, shorter shelf-life and foodborne illnesses. Potential sources of contamination include: processing environment, type of circulation water, surface contact, working practices (Good Hygiene Practices), pest infestation, storage of raw material and food packaging material (Pirttijärvi,2000; Sjöberg *et al.,* 2002). This is the reason why several

national and international standards were developed and enforced for food packaging material manufacturing such as BRC for

packaging and packaging material, ISO 22000:2005 technical specification ISO/TS 22002-4, USA's FDA food safety modernization act (FSMA), European Union's (EC) No. 1935/2004, and Lebanon's LIBNOR NL EN 13427:2007 and NL EN 15593:2012. Even though these standards are available there is no baseline information on the extent of adherence to them by Lebanese food packaging companies. Based on those requirements, the hygienic status is assessed by prerequisite programs (PRPs) evaluation and verified by objective measurements. PRPs assessment is based on the evaluation of: establishment layout and workspace, utilities, waste disposal, equipment suitability, cleaning and maintenance, management of purchased materials and services, measures for prevention of contamination, cleaning, pest control, personnel hygiene and facilities, rework, withdrawal procedures, storage and transport, food packaging information and customer communication, food defense and bioterrorism (ISO/TS 22002-4:2013). Hence the need of inspection, audit, routine monitoring and verification methods of PRPs. Objective measurements can include testing of contact surface, employee hand, packaging material, ambient air, and water. Total aerobic count and *Enterobacteriaceae* are common indicators for the three objective measurements in addition to *Staphylococcus aureus* for employee hand testing and yeast and molds for food packaging material (Guzińska *et al.,* 2012; Mashhadi *et al.,* 2015; Garayoa *et al.,* 2016; Losito *et al.,* 2017; Valero *et al.,* 2017; Illés *et al.,* 2018; Zaman *et al.,* 2018; Sood and Sharma, 2019). Studies in the literature showed carried out PRPs evaluation mainly in catering and food production (Bas *et al.,* 2005; Bas *et al.,* 2006; Costa Dias *et al.,* 2012;

Liz Martins and Rocha, 2014; Luning *et al.,* 2015; Tavakkoli *et al.,* 2015; Garayoa *et al.,* 2016; Trafialek *et al.,* 2019). However, despite the importance and impact of packaging on all food sectors, no published studies were

available in food packaging companies. The aim of this study was to evaluate the PRPs implementation in food packaging companies across Mount Lebanon and to assess the compliance of contact surfaces, employee hands and packaging materials to microbiological specifications.

2. Materials and Methods

2.1 Food packaging companies

A cross-sectional study was conducted throughout February 2020 till July 2020 targeting food packaging companies across Mount Lebanon. Five companies were chosen as a probability random sample of registered food packaging companies in Mount Lebanon. The characteristics of the companies are shown in Table 4. An initial contact with the top managers of the selected companies was scheduled (mobile conversation followed up with an email). Each company was visited by the same trained person in food safety and PRPs, in order to conduct the face-to-face interviews, carry out the inspection and collect the samples. The duration of the visit was approximately 1-2 hours.

Table 4. Company characteristics of food packaging companies (n = 5)

Company	Packaging Type	Intended Use	Food Application	Quality/food safety management system
A	Plastic Bottles, gallons	RTE	Ketchup & Lemon Substitute Juice	ISO 9001:2015

B	Bags, flexible packaging	Freezing, vacuum packaging, modified atmosphere packaging, RTE	Bakery products, cereals & spices, nuts, seafood, coffee, dairy food, fresh & frozen food	None
C	Bags, flexible packaging, wrappers, pallets	Heating, freezing, microwave, boil in bags, vacuum packaging, modified atmosphere packaging, collation shrinking, RTE	Bakery products, candy & chocolates, cereals & spices, dry food, nuts, seafood, coffee, dairy food, chips, fresh & frozen foods, instant drink, pet food packaging	None
D	Trays, plastic containers	Heating, freezing, microwave, re-use, RTE	Bakery products, candy & chocolates, spices, dry food, nuts, dairy food, fresh & frozen foods, instant drink	ISO 9001:2015
E	Flexible packaging, wrappers	Freezing, vacuum packaging, modified atmosphere packing, RTE	Bakery products, candy & chocolates, cereals & spices, dry food, nuts, seafood, coffee, dairy food, chips, fresh & frozen foods, instant drink	None

Data collection took place after obtaining the ethical approval of the International Review Board (IRB) at Notre Dame University (NDU); approval number (Ref #:IRBSP2019_3_FNHS). A written informed consent form was signed by the companies' staff participating in the study.

2.2 Questionnaire

The developed questionnaire consisted of two parts. The first part covered the general company characteristics and was adapted from De Boeck *et al.* (2018). It described information related to the company production sector, intended use/application, certification(s), etc.. The second part of the questionnaire included an inspection checklist

prepared according to ISO/TS 22002-4:2013 and Libnor standard NL EN 15593:2012. 15 main clauses were thus evaluated and included: establishment layout and workspace, utilities, waste disposal, equipment suitability, cleaning and maintenance, management of purchased materials and services, measures for prevention of contamination, cleaning, pest control, personnel hygiene and facilities, rework, withdrawal procedures, storage and transport, food packaging information and customer communication, food defense and bioterrorism. In order to enable a differentiated assessment, each clause/sub-clause was scored according to the following four situational descriptions of performance levels: No compliance (score 0/2), partial compliance (score 1/2), full compliance (score 2/2) and Not applicable (N/A) (score 0/0). Scoring of each main clause was obtained based on total score of its sub-clauses or its own score in the case of absence of sub clauses. The total score was obtained by adding all the scores of the main clauses. Both main clauses and total scores were converted to a score over 100 and calculated into percentages rounded to the nearest whole number.

2.3 Collection of hand and surface swab samples

Hand and surface swab samples were collected according to ISO 18593:2004. Hand samples from packaging handlers were collected from both hands during regular working activities from two workers directly handling packaging material at the end point of the production line before warehouse storage or distribution (Zaman *et al.*,2018; Garayoa *et al.*, 2016). Similarly, surface swab samples were collected from surfaces in direct contact with packaging material at the end point of the production line before storage (Garyoa *et al.*, 2016). Target surface areas were delimited by a stainless-steel sterilized template of

25 cm^2 and swabbed using a sterile cotton wool swab (Citoswab; China) moistened with transport-neutralized solution of Letheen broth (Scharlau; Spain). Surfaces were rubbed for 20 s and then introduced into the transport tubes.

2.4 Collection and preparation of packaging samples

Packaging samples were collected from both the inspected companies and the retail market. A total of ten samples were collected from the 5 visited companies (2 packaging samples from each company). Additionally, 20 samples were obtained from a representative retail packaging distribution company that supplies several catering and food companies in different areas of the country. Four packaging samples were randomly selected from each of the following 5 categories: dairy/ ice cream containers, salad/bakery/meat containers, ready to eat (RTE) mezze containers, sauce cups with lids (<100ml) and dessert/fruit cups with lids. The criteria for category selection were risk-based and included packaging intended to be used without further sterilization or cleaning before coming in contact with food or intended for packaging perishable high risk products, or ready-to-eat food with a shelf-life of several days to few weeks (Feichtinger *et al.,* 2015). Flexible plastic packaging samples were swabbed as described for contact surfaces in section 2.3. Rigid Plastic packaging containers were tested using the rinse method. Each container was rinsed with 300 ml of Letheen broth (Scharlau; Spain) then shaken for 30 seconds. The liquid was then filtered using Cellulose Nitrate (CN) membrane filter 0.45 µm (Sartorios; Germany) and passed through 47mm filtration assembly (Wheaton, USA) using pressure differential

vacuum of 400 mm Hg (Corning; USA). CN was then placed on appropriate agar media (section 2.5).

2.5 Microbiological analysis

Collected samples were immediately transported to the laboratory in containers with ice and kept refrigerated (1 to 4°C) until the start of the microbiological analysis (<4 h from collection). Tests were carried out at the Industrial Research Institute (I.R.I.) which is accredited by ANSI National Accreditation Board (ANAB) lab for International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ilac-MRA).

Contact surfaces and hand samples were analyzed for total viable count (TVC) and *Enterobacteriaceae* while packaging samples were additionally tested for yeasts and molds following 'FDA, Bacteriological Analytical Manual, AOAC, International, chapter 23' (Huang et al.,2017). The filter from the rinse method or 10-fold dilutions from the transport liquid of the swab samples were plated on appropriate agar media. TVC was enumerated on tryptic soy agar (TSA) (CASO agar; Merck) and incubated for 72 ±3 h at 30 ± 1 °C. *Enterobacteriaceae* enumeration was on Violet Red Bile Glucose Agar (VRBG) (Scharlau; Spain) after incubation for 24 ± 2 h at 37 ± 1 °C and for yeasts and molds, Sabouraud Dextrose Agar (SDA) (Bio-Rad,USA) was used for 5 days at 25 °C. Tests were conducted in replicate and results were reported as mean values ± standard deviation (SD). All colonies were counted on each plate and counts per sample were reported as mean colony forming units (CFU) per cm^2 for contact surface and flexible packaging, per employee

hands swabs and per container for rigid plastic packaging. Values were then converted to logarithms of the number of CFU per respective unit (cm^2, hands, container).

3. Results and Discussion

3.1. Overall compliance to PRPs requirements

Following on-site inspection, none of the companies achieved a full total score of 100% (Table 5). Total scores for companies ranged from the highest being 62% (company D) to the lowest being 25% (company A) (Table 5). Remaining scores for companies C, B and E were 56%, 53%, and 51% respectively (Table 5). It is noteworthy that the companies with the highest and lowest scores had a quality management system (QMS) certification for ISO 9001, while the 3 other companies didn't have any quality or safety system (Table 4). However, those scores cannot be correlated to the presence or absence of QMS which does not address PRPs. Similar results were seen for catering services located in northern Spain (n=15) where none achieved the maximum score (43), with total scores ranging from 19 to 36 points (Garayoa *et al.,* 2016). In addition, a study conducted on government and private hospitals evaluation in Ankara, Turkey (n=20) also had similar results where the overall mean score on the prerequisite questionnaire for hospital food service was 57.5% (Bas *et al.,* 2005).

Out of the five companies assessed, 20% achieved full compliance (100 % score) for clauses related to establishment, management of purchased materials and services, rework and 40% achieved full compliance for clause food packaging information and customer communication (Table 5). Non-compliance (0% score) was registered for 20% of the

companies for clauses related to measures for prevention of contamination and food defense and bioterrorism (Table 5). Clause related to rework was not applicable in 40%

of the companies (Table 5). Partial compliance was observed in all companies for the remaining clauses: layout and workspace, utilities, waste, equipment suitability, cleaning and maintenance, cleaning, pest control, personnel hygiene and facilities, withdrawal procedures, storage and transport ranging from a minimum score of 7% to a maximum score of 94 % (Table 5). Similarly, in food businesses assessed in Turkey (n=109), PRPs proper food safety practices were often not being followed in many food businesses i.e., personal hygiene, equipment cleaning and sanitation, and general sanitation procedures (Bas *et al.*, 2006).

Company A is specialized in production of plastic bottles and gallons for food and non-food applications. However, the quality objectives focused mainly on product density and thickness rather than safety or hygienic status of packaging. The lowest score was full non-compliance (0% score) for clause related to measures for prevention of contamination (Clause 4.7, Table 5), and the highest was 69% for management of purchased materials and services (Clause 4.6, Table 5). The facility was an old building located within close vicinity to industrial zone and did not keep all areas within boundaries in conditions that will protect against contamination. Those may be some of the factors that can explain the lowest total score for this establishment (Table 5).

On the other hand, company B, was a recent building in addition to the construction of a newer facility. It showed full compliance (100%) to the clause related to establishment (Clause 4.1, Table 5) by giving full consideration to the potential sources of contamination from the local environment in its new building and was fully protected against sources of contamination. The lowest score was for clause of food defense and bioterrorism 12% (Clause 4.15, Table 5). The company specialized in food packaging

production, had a big portion of the market share, had more staff members with specified departments and the production manager was in charge of quality.

Company C was also located within close vicinity to industrial zone and did not keep all areas within boundaries in a condition that will protect against contamination. However, it showed full compliance (100%) to clauses related to rework (storage, identification and traceability, and usage), food packaging information and customer communication (Clauses 4.11 & 4.14, Table 5). Non-compliance (0% score) was recorded for food defense and bioterrorism (Clause 4.15, Table 5). The plant manager had full awareness of the clauses but explained the difficulty of implementing them, due to budgeting reasons. Most matters that did not incur additional costs and required staff effort such as research, documentation was in partial or full compliance.

Company D had the highest score and achieved full compliance (100%) for food packaging information, customer communication and management of purchased materials and services (Clauses 4.6 & 4.14, Table 5). Lowest score was observed for the utilities clause 33% (Clause 4.3, Table 5). The company took part in European tradeshows and had

certified international suppliers and customers that set specific requirements that were met. Management commitment was noticeable and willingness for future certifications was in the pipeline.

Company E had specialized personnel and the quality manager showed strong knowledge of the standard. In addition to standard requirements, there was deep knowledge by the quality manager of chemical properties of all raw material used, tests that need to be

conducted, and safety of solvents used. Entry to the facility was not granted without permission, and facility layout was properly segregated within limited space given. Highest score was achieved for management of purchased materials and services 81% (Clause 4.6, Table 5); and the lowest one was for clause of food defense and bioterrorism 12% (Clause 4.15, Table 5). In addition to system documentation requirements, needed certificates such as treatment certificate for wooden pallets were present only in company E. All necessary documentation was present, and this facilitated data transfer and answering several questions related to standard requirements.

3.2. Assessment of compliance to specific PRPs requirements

Regarding layout and workspace companies B and E (40 %) were spacious enough to allow a logical flow of materials, products and people through the production process. Similarly, adequate facilities for meals production were found in all food units evaluated in schools (n=88) at Portugal (Liz Martins and Rocha, 2014). None of the companies had drains, cleaning with water was not part of the routine process and when used it was swept

in the direction outside the company towards the nearest entrance/exit. Additionally, standing water was present on-site in companies A and D (40%).

Company A (20%) had a dedicated separate floor for storage of wrapped raw material and shrink-wrapped finished products protecting them from dust and contamination with proper segregation of raw materials, intermediate materials, chemicals and finished food packaging. Similar compliance was found in found in all school foodservice evaluated where food storage in adequate containers and freezing and refrigeration temperature

documentation were good practices (Liz Martins and Rocha,2014). The remaining companies did not store raw material rolls far enough from production zones and other sources of contamination. Companies B and D (40%) took some preventive measures (pallets, wrapping, removing first side of the roll that was exposed to the environment) while the remaining companies C and E (40%) did not. Similar to our study for catering services in northern Spain, the most important non-conformities were the insufficient storage space for foods (60%) and repeated deviations were not enough storage capacity in warehouses, and poor stock rotation (66.7%) (Garayoa *et al.*, 2016). In addition, all great chain restaurants in Iran had poor condition for storage (Tavakkoli *et al.,* 2015), and inadequate number of storerooms were seen in foodservice at hospitals in Turkey (Bas *et al.,* 2005).

For utilities, only company E (20%) had established requirements for water and separate supply of potable water, while A, B, D (60%) used a reverse osmosis water purification device. Company C (20%) did not take any additional measures to the non-potable water supply. None of the companies had established requirements for air used in direct contact with packaging material.

Regarding waste, none of the companies had clearly identified bins to differentiate between production and non-production waste. Similar findings regarding non-compliance was observed in catering services in northern Spain, where repeated deviations included absence of dustbins with pedal (40%) in the preparation and cooking areas (Garayoa *et al.,* 2016). In addition, incorrect handling of waste was found in all foodservices evaluated in Portugal (Liz Martins and Rocha, 2014).

Equipment hygienic design and food packaging contact surfaces were not suitable in all companies. Company B (20%) had the correct design however placed leather and scotch tape on the final counters. Company E (20%) had wooden surfaces covered with nylon and the remaining companies A, C, D (60%) did not place any measures for non-compliant surfaces.

For maintenance, companies C, D, E (60%) had a system of planned preventive maintenance whereas A and B (40%) only performed corrective maintenance on need basis. Similarly, for catering services in northern Spain, one of the most important deviations were the lack of a maintenance plan for facilities and equipment (40%) (Garayoa *et al.,* 2016).

Concerning measures for prevention of contamination, only company E (20%) carried out and documented a hazard analysis for prevention of contamination. The hazard analysis was prepared for future plans of certification but was not fully implemented yet. Proper documentation was missing in most companies, since none was certified against food safety standards. Similarly, none of the great chain restaurants visited in Iran had adequate quality for documentation (Tavakkoli *et al.,* 2015). On the other hand, in children's nurseries in Warsaw, results showed that the level of compliance with both GMP/GHP and HACCP standards was high in respect of documentation not practice (Trafialek *et al.,*2019). For microbial contamination, companies A and C (40%) had no implemented measures (Clause 4.7, Table 5). Even though company E was the only company with documented hazard analysis including microbial hazards; it did not fully mitigate the risk along with companies B and D (60%). Few considerations were made in this regard such as changing compressed air filter in company, facility layout air flow

from least contaminated to most contaminated and proper cleaning. Similar to our findings regarding contamination, repeated deviation included food products in contact with the floor (40%) for catering services in northern Spain (Garayoa *et al.*, 2016).

In cleaning clauses, companies C and D (40%) had daily cleaning schedule after production and proper monitoring program (Company D). Companies A and B (40%) had none (Clause 4.8, Table 5). Company E had a documented cleaning program but did not fully monitor its effectiveness. Similarly, in food businesses assessed in Turkey, failure in food-handling practices were related to the cleaning and sanitation of utensils, equipment, and cleaning and sanitizing of the food contact surface was not observed in 39

of the food businesses (Bas *et al.,* 2006). In addition, non-conformities were observed in all foodservice units in Portugal on cleaning and disinfection practices of equipment and facilities (Liz Martins and Rocha, 2014). In all companies cleaning agents were clearly identified, stored separately and used only in accordance with the manufacturer's instructions.

For pest control, companies B, C and D (60%) outsourced their pest control programs, which showed good compliance (Clause 4.9, Table 5). However, partial or non-compliance was observed for covering external doors, windows or ventilation openings to prevent entry of pests. Company B also did not have enough rodent bait stations and traps. The remaining companies A and E (40%) performed in-house control; which showed poor compliance (Clause 4.9, Table 5). Even though no pests were seen at the time of visit; however, policies, documentation and records of used materials were not compliant.

Regarding personnel hygiene and facilities, all personnel, visitors and contractors in companies B and E (40%), were required to comply with the visual instructions and signs (posters at the entrance door, entrance only allowed with presence of personnel in charge, hair nets present at the door). In company D (20%), oral instructions were given to visitors to wear hair nets. The remaining companies A and C (40%) did not have any procedure in place (Clause 4.10, Table 5). Majority of the companies (A, C, and D) (60%) did not have any hand washing stations present in the production area. Company B (20%) had one hand washing station for a shift of minimum fifteen employees and hand washing was done in staff wash room. Company E (20%), had more than one station but still was

not sufficient to recommended staff ratio (1-9 employees per 1 hand washing station). Similar to our study, lack of specific sinks for hand washing (73.3%) was a repeated deviation in catering services in northern Spain (Garayoa *et al.*, 2016), and in hospital food service in Turkey in addition to inadequate numbers of toilets for food service staff and overall mean score on personnel hygiene scores were 55.3% ± 14.7% (Bas *et al.*, 2005). In addition, lack of dedicated hand washing sink in food preparation and distribution areas with proper drying setting was observed in 60% of meal production units at schools (Liz Martins and Rocha, 2014).

Staff canteens were not appropriately located in companies A and B (40%), they were not isolated by closed doors (Company B) and their access route was through production area (Company A) (Clause 4.10, Table 5). In addition, employees stored their food in the production areas in a refrigerator (company A) or under the production counter (company B). Companies D and E (40%) had dedicated space but employees' behavior and

practices were not fully compliant. Only company C (20%) had a more spacious facility with properly designed and situated canteen. Similarly, food businesses assessed in Turkey, employees were observed eating and drinking in the food-service areas (Bas *et al.*, 2006).

Gloves were not in clean condition in companies A and E (40%) but were used properly in companies C and D (40%). Company B (20%) provided gloves that were in clean conditions for majority of employees; but some employees did not comply. Hair nets were worn by all employees of Company D (20%) whereas not all employees complied and wore them in companies C and E (40 %), and none in company A and B (40%). Personal cleanliness was most compliant in company D, since there is a designated employee for follow up, however full compliance was not granted due to the lack of hand washing stations in production areas. Additional preventive measures such as face masks were worn in companies C and E (40%) since visits were conducted during COVID-19 pandemic, which increased overall PRP compliance.

Table 5. PRPs checklist compliance scores

	Company Compliance Scores (%)				
Clause	**A**	**B**	**C**	**D**	**E**
4.1 Establishment	60	100	30	50	60
4.2 Layout and workspace	39	58	33	47	47
4.3 Utilities	20	53	27	33	43
4.4 Waste	33	50	42	92	50
4.5 Equipment suitability, cleaning and maintenance	27	42	58	42	50
4.6 Management of purchased materials and services	69	50	69	100	81
4.7 Measures for prevention of contamination	0	39	64	41	64
4.8 Cleaning	17	50	58	50	67
4.9 Pest Control	19	87	94	94	44
4.10 Personnel hygiene and facilities	7	14	45	57	43
4.11 Rework	21	N/A	100	85	N/A
4.12 Withdrawal Procedures	25	75	50	50	50
4.13 Storage and transport	32	59	71	73	73

4.14 Food packaging information and customer communication	33	87	100	100	25
4.15 Food defence and bioterrorism	12	12	0	37	12
Total Score	25	53	56	62	51

3.3. Assessment of hygienic status of contact surfaces

Poor sanitation of food contact surfaces, equipment, and processing environments have been an important factor in foodborne outbreaks (Pieniz *et al.*,2019). Assessing the hygienic status of contact surfaces is a common objective measurement of assessing cleaning practices in factories (Garayoa *et al.*, 2014; Garayoa *et al.*, 2016; Doménech-Sánchez *et al.*,2011; Pieniz *et al.*,2019). In order to assess the hygienic status of surfaces in contact with food packaging, 2 surface swab samples were collected from all the companies as shown in Table 6.

Surface cleanliness was evaluated based on acceptable limits of ≤ 0.6 log CFU/cm^2 and 0 log CFU/cm^2 for TVC and *Enterobacteriaceae*, respectively. There are no unified set limits for contact surfaces cleanliness and the ones used were based on established criteria in other studies (Garayoa *et al.*, 2014; Garayoa *et al.*, 2016). Non-conforming results were observed in 50% (5/10) of the surfaces (Table 6). Highest counts of 1.3 log CFU/cm^2 were from metal box for ketchup gallon (Company A), scotch taped counter for frozen fish bag (Company B), Cheese container machine line (Company D), bag machine forming shoulder surface (Company E) (Table 6). Other non-conforming results at 1.1 log CFU/cm^2 were observed on the dessert container machine line (company D) (Table 6). Lower conforming levels at 0.4 log CFU/cm^2 were from metal box collector for lemon

substitute bottles (Company A) and scotch taped counter for ready to eat beef vacuum bag (Company C) (Table 6). Remaining conforming results were below detectable limit for swabs from end of line leather counter (Company B), wooden surface (Company C), and roller of slitting machine (Company E) (Table 6). Regarding *Enterobacteriaceae*, all samples were acceptable and showed results below the detection limit (Table 6).

Company C had 100% (2/2) compliant results for surface samples. Conformance varied between below limit of detection for wooden surface and 0.4 log CFU/cm^2 for scotch taped counter (Table 6). The scotch taped counter was made from one layer and had no to barely visible gaps between lines of tape; whereas the wooden surface was smooth and easily cleanable.

Companies A, B, and E had 50% (1/2) compliant results for surface samples. Samples taken from the same company A were non-conforming (1.3 log CFU/cm^2) for the metal box for ketchup gallon and conforming (0.4 log CFU/cm^2) for the collector of lemon substitute bottles (Table 6). In company B, compliance was observed in counter covered with leather (below detectable limit <1 log CFU/cm^2) and non-compliance in scotch taped counter for frozen fish bag (1.3 log CFU/cm^2) (Table 6). Finally, in company E, compliance was observed in roller of slitting machine (below detectable limit <1 log CFU/cm^2) and non-compliance in bag machine forming surface 1.3 log CFU/cm^2) (Table 6). Where variant results were found in the same companies; it was observed that the surfaces tested had different levels of smoothness and ease of cleaning i.e. ridges in the metal box for ketchup gallon collection (Company A), smooth surface provided by the leather cover versus non-uniform scotch tape showing gaps between layers (Company B), the frequency and ease of cleaning the slitting roll versus the difficulty in cleaning the

forming shoulder (Company E). Along with adherence to proper hygienic design and use of suitable contact materials, there should be constant checking and replacement of damaged surfaces (Garayoa *et al.,* 2016).

Whereas, company D, showed 100% (2/2) non-compliant results for surface samples. Non-conformance varied between 1.3 log CFU/cm^2 and 1.1 log CFU/cm^2 for different machine lines (Table 6). Both lines were made from similar material.

It was observed that equipment hygienic design and food packaging contact surfaces were not fully compliant in all companies where scores varied for equipment suitability, cleaning and maintenance between 27% (company A) and 58% (company C) (Clause 4.5, Table 5). In addition, proper cleaning programs should be put in place, resources (utensils and detergents) should be supplied, and proper monitoring and verification programs should be followed (Garayoa *et al.,* 2016).

Following the same criteria, the percentage of conformity was lower for TVC and higher for *Enterobacteriaceae* in catering services located in northern Spain (n=15). 86.7% and 96.7% of food contact surfaces were conforming to the mesophilic aerobes (MA) and *Enterobacteriaceae* criteria, respectively, showing good cleaning and disinfection standards (Garayoa *et al.,* 2016). Higher counts of TVC and *Enterobacteriaceae* were related to lower total checklist scores (Garayoa *et al.,* 2016). Our study results were also lower than a study conducted in Navarra (Spain) (n=600) to assess surface hygiene control in two catering services where only 15.9% of the surfaces exceeded the limit of 0.6 log CFU/cm^2 for TVC (Garayoa *et al.,* 2014).

Following more lenient criteria (TVC < 1.3 log CFU/cm^2), higher percentage of conformity (74%) was observed on food contact surfaces (n=4611) in hotels (n=280) in Spain (Doménech-Sánchez *et al.*,2011).

Table 6. Microbiological counts of swab samples collected from surfaces in contact with food packaging materials at the end of the production line.

Company	Surface description	Packaging type	Total Viable Count (log CFU/cm^2 ± SD[a])	*Enterobacteriaceae* (log CFU/cm^2±SD[a])
A	Surface 1	Ketchup gallon	1.3 ±0.02	<DL[b]
	Surface 2	Lemon substitute bottle	0.4 ±0.01	<DL [b]
B	Surface 1	Smoked Salmon Vacuum Bag	<DL [b]	<DL [b]
	Surface 2	Frozen Fish Bag	1.3 ±0.02	<DL [b]
C	Surface 1	Beef Vacuum Bag	0.4 ±0.01	<DL [b]
	Surface 2	Zip-lock Bag	<DL [b]	<DL [b]
D	Surface 1	Cheese Container	1.3 ±0.02	<DL [b]
	Surface 2	Dessert Container	1.1 ±0.02	<DL [b]
E	Surface 1	multipurpose vacuum bag	<DL [b]	<DL [b]
	Surface 2	multipurpose vacuum bag	1.3 ±0.02	<DL [b]

[a] Standard Deviation
[b] Detection Limit =10 CFU/25 cm^2

3.4. Assessment of hygienic status of employee hands

Assessing the hygienic status of employee is a common objective measurement of assessing personnel hygiene practices in factories (Tan *et al.*,2013; Garayoa *et al.,* 2016; Tomasevic *et al.*,2016; Valero *et al.,* 2017). Hand samples were taken from end of line employees in all companies as shown in Table 7.

There are no unified set limits for cleanliness of hand employees. Studies that aimed at assessing hand swabs to determine effectiveness of hand washing, only determined presence or absence of bacteria (Garayoa *et al.,* 2016; Valero *et al.,* 2017). In other studies, the set limits for hand swabs were the same as limits used for contact surface conformity assessment (Tan *et al.*,2013; Tomasevic *et al.*,2016). The findings of our study were the same whether adopting the presence or absence criteria or the less stringent one with acceptable limits of $\leq$ 0.6 and 0 log CFU/hands for TVC and *Enterobacteriaceae,* respectively (Garayoa *et al.,* 2014; Garayoa *et al.,* 2016).

None of the hand swab samples was conforming for TVC that was present in all samples above the acceptable limit but all the samples were below the detectable limit for *Enterobacteriaceae* (Table 7).

Highest value and lowest values were found respectively in company D for employee on dessert container line at 4.4 log CFU / hands, and in company A for employee on lemon substitute bottle line at 1.7 log CFU/ hands (Table 7).

All the companies had generally low scores ranging from 7 to 57 % for personnel hygiene and facilities (clause 4.10, Table 5). This was mainly attributed to the lack of or insufficient number of handwashing stations. The unsatisfactory results emphasize the

need for adequate supply of hand washing stations, regular training for employees on proper hand washing technique and provision of soap, disposable tissues, and sanitizer. This is supported by previous work in Spain that showed that mesophilic aerobic microorganisms, *Staphylococcus* spp. and *Enterobacteriaceae* were respectively present in 91.3, 53.3 and 22.8%, of the food workers' hands before washing, while significant reduction of microbial load was obtained on all bare or gloved hands after washing (Garayoa *et al.,* 2016).

In addition to hand washing, training should include all general hygiene practices e.g. refraining from touching their face, food, drinks, waste bins, and cigarettes, proper usage of gloves, proper nail trimming, and frequency of hand washing. The proper adherence to these practices should also be monitored regularly by designated employee to ensure training efficacy. It is important for employees to understand the sources of contamination and the route of spread from their hands to end product (Patrignani *et al.* 2016; Garayoa *et al.,* 2016; Valero *et al.,* 2017); especially since all packaging material are counted and sorted manually after processing. Similarly, *Enterobacteriaceae, Escherichia coli, and Staphylococcus aureus* were present in 62.1, 7.5 and 26.6% of food handlers' samples during food preparation for collective meals in Spain, respectively (Valero *et al.,* 2017). In Malaysia, the aerobic plate count reported on the employee's hands was only 20, 28, and 29% acceptable before, after, and during ready to eat preparation, respectively (Tan *et al.,* 2013).In addition, it must be pointed out that TVC counts varied between one employee and another in the same company. For example, results varied between 2.6 and 4.4 log CFU/cm^2 in company D and between 1.3 and 3.1 log CFU/cm^2 in company E (Table 7). Those differences showed the importance of

strengthening food safety culture, employee's behavior and refresher trainings; especially that only 3 companies (60%) reported conducting more than 1 food safety training per year.The significance of effectiveness of PRPs implementation can show tangible results on the reduction of bacterial load. This was demonstrated in a study conducted in Serbia in meat processing plants and meat retail, where hand swab acceptability (TVC ≤ 2.7 log CFU/cm^2), increased from 47.29-48.9 to 97-98.96 % before and after HACCP implementation, respectively (Tomasevic *et al.*,2016).

Table 7. Microbiological counts of swab samples collected from employee hands in contact with food packaging materials at the end of the production line.

Company	Surface description	Packaging type	TVC (log CFU/hand ± SD[a])	*Enterobacteriaceae* (log CFU/hand± SD[a])
A	Operator1	Ketchup gallon	3.0 ±0.04	<DL[b]
	Operator 2	Lemon substitute bottle	1.7 ±0.03	<DL[b]
B	Operator 1	Smoked Salmon Vacuum Bag	2.9 ±0.04	<DL[b]
	Operator 2	Frozen Fish Bag	3.3 ±0.05	<DL[b]
C	Operator 1	Beef Vacuum Bag	4.3 ±0.06	<DL[b]
	Operator 2	Zip-lock Bag	3.2 ±0.05	<DL[b]
D	Operator 1	Cheese Container	2.6 ±0.04	<DL[b]
	Operator 2	Dessert Container	4.4 ±0.07	<DL[b]
E	Operator 1	multipurpose vacuum bag	1.3 ±0.02	<DL[b]
	Operator 2	multipurpose vacuum bag	3.1 ±0.05	<DL[a]

[a] Standard Deviation
[b] Detection Limit =10 CFU/ hand

3.5. Assessment of hygienic status of food packaging samples

Packaging samples used for RTE products were collected from the 5 companies to check their hygienic quality and from retail market to simulate different routes of contamination along the supply chain. There are no standard microbiological criteria for packaging material, however manufacturers generally followed Food and Drug Administration (FDA) guidelines for dairy products (Pirttijärvi *et al.*,2000; Ibrahim and Sobeih, 2010; FDA, 2017). According to the bacterial standards, the TVC count of single-service containers and closures, used for packaging pasteurized milk and/or milk products, should be <50 CFU/Container (<1.7 log CFU/container), <10 CFU/Container (1 log CFU/container) with capacity less than 100ml using rinse test and <1 CFU/cm^2 (0 log CFU/container) using swab test (FDA, 2017). They should also be free of coliform organisms (Pirttijärvi *et al.*,2000; Ibrahim and Sobeih, 2010; FDA, 2017). Regarding yeasts and molds limits were <1 fungal CFU/dm^2 (Suihko and Skyttä, 1997).

For the samples collected during on-site inspections, TVC and yeasts and molds were detected within the acceptable limit in 20% (2/10) of the samples (Table 8). *Enterobacteriaceae* were not detected in all samples (Table 8). In company D, TVC (0.7-0.8 CFU), yeast and molds (0.3-0.8 CFU) were detected in both dessert and cheese containers (Table 8). In addition, the score of company D was only 41% on the clause related to prevention of contamination (Clause 4.7, Table 5).

Table 8. Microbiological counts of food packaging samples collected during on-site inspection

Company	Packaging Sample	Test method	Total Viable Count (log CFU /Container or /cm^2 ± SD[a])	*Enterobacteriaceae* (log CFU /Container or /cm^2 ± SD[a])	Yeasts & Molds (log CFU /Container or /cm^2 ± SD[a])
A	Ketchup Gallon	Rinse test	<DL[b]	<DL[b]	<DL[b]
	Lemon Substitute Bottle	Rinse test	<DL[b]	<DL[b]	<DL[b]
B	Smoked Salmon Vacuum Bag	Swab test	< DL[c]	< DL[c]	< DL[c]
	Frozen Fish Bag	Swab test	< DL[c]	< DL[c]	< DL[c]
C	Beef RTE Vacuum Bag	Swab test	< DL[c]	< DL[c]	< DL[c]
	Dairy RTE Vacuum Bag	Swab test	< DL[c]	< DL[c]	< DL[c]
D	Cheese Container	Rinse test	0.7 ±0.01	<DL[b]	0.3 ±0.0
	Dessert Container	Rinse test	0.8 ±0.01	<DL[b]	0.8 ±0.01
E	Ready To Eat Humus bag	Swab test	< DL[c]	< DL[c]	< DL[c]
	Multipurpose Vacuum bag	Swab test	< DL[c]	< DL[c]	< DL[c]

[a] Standard Deviation
[b] Detection Limit =1 CFU/Container (Rinse test)
[c] Detection Limit =10 CFU/ 25 cm^2 (Swab test)

As for the samples collected from the retail market, TVC were detected in 95 % (19/20) of samples (within set acceptable limit) (Table 9). The highest TVC count was 1.6 log CFU/Container for one container from salad/bakery/meat category (Table 9). Yeasts and molds were detected in 65% (13/20) of the samples with the highest value in a dairy/ice cream sample at 1.1 log CFU/Container (Table 9). However, none of the samples was above the selected acceptable limit. *Enterobacteriaceae* were below detection limit with 100% (20/20) compliance in all the samples (Table 9).

Table 9. Microbiological counts of food packaging samples collected from retail market using rinse test method

Category	Total Viable Count log CFU/Container	*Enterobacteriaceae* log CFU/Container	Yeasts & Molds log CFU/Container
1. DAIRY/ ICE CREAM CONTAINERS	1.4	< DL[aa]	1.1
	0.3	< DL[a]	< DL[a]
	0.7	< DL[a]	0.3
	1.0	< DL[a]	0
2. **SALAD/BAKERY/ MEAT CONTAINERS**	1.4	< DL[a]	0
	0.3	< DL[a]	< DL[a]
	1.6	< DL[a]	0.3
	0.7	< DL[a]	0
3. MEZZE CONTAINERS	1.3	< DL[a]	0.7
	0.6	< DL[a]	0.3
	1.2	< DL[a]	0
	0	< DL[a]	0.3
4. SAUCE CUPS WITH LIDS	0.9	< DL[a]	0.3
	0.6	< DL[a]	0.3
	< DL[a]	< DL[a]	< DL[a]
	0.3	< DL[a]	< DL[a]
5. DESSERT/FRUIT CUPS WITH LID OPENING	0.3	< DL[a]	< DL[a]
	1.3	< DL[a]	< DL[a]
	0.3	< DL[a]	< DL[a]
	1.4	< DL[a]	0.3

[a] Detection Limit =1 CFU/Container (Rinse Test)

Overall counts of samples taken from the retail market were higher than the ones from companies for TVC and yeasts and molds; however, *Enterobacteriaceae* results were all the same. This can be attributed to the additional sources of contamination during transportation, distribution, handling, storage, and retail display and highlight the importance of control measures along all the supply chain.

Even though the samples were within the acceptable limits, the presence of microorganisms can be a concern when the packaging will get in contact the food. The counts of TVC and yeasts and molds that were detected; were present on packaging material intended to be in direct contact with RTE food (cheese, dessert, salad, bakery, meat) without any further sterilization process. The effect of these counts, their interaction with stored foods, presence of nutrients and other growth factors can increase the bacterial load in the food (Ibrahim and Sobeih, 2010; Steinka, 2015). Packaging materials can thus be a source of microflora which can influence food products in terms of safety and quality (Steinka, 2015).

Several other studies showed higher microbial counts on food packaging materials. Egyptian soft cheese plastic containers and cardboard laminated packages had mean Aerobic plate counts of 4.49×10^3 CFU/Package (3.6 log CFU/package) and 1.17×10^3 CFU/ cm^2 (3.1 log CFU/cm^2), respectively (Ibrahim and Sobeih, 2010). In Bangladesh flexible intermediate bulk food containers showed counts of TVC (2.06 ± 0.08 log CFU/unit) and *Staphylococcus* spp. (1.78 ± 0.01 log CFU/unit) in the spout top of the bags; indicating handling by employees with contaminated hands (Zaman *et al.*,2018). On the other hand, the spout bottom was found clean but after enrichment, the presence

of stressed coliforms was evident (Zaman *et al.*,2018). However, Salmonella spp. was not found in any samples analyzed (Zaman *et al.*,2018). In a production line for plastic caps for soft drink bottles filled according to the aseptic method, the raw materials including the base resin, the master batch, and the linear material indicated an average of 0.9 filamentous fungi per sample (Sato, 2010). In another study, eight food grade cling film samples purchased from supermarkets in Iran (n=15), had bacterial contamination with three different bacterial strains of *Bacillus* spp. (except *B. anthracis*), *Klebsiella* spp. and coagulase positive *Staphylococcus* spp. (Mirzaei *et al.*,2016).

4. Conclusions

PRPs assessment and verification activities showed the need for companies to strengthen their PRP planning and implementation such as: proper cleaning programs, frequent training on personnel hygiene and hand washing practices. Recommendations extend to all companies visited since even the companies with the highest scores had contamination problems. Food packaging companies should direct more effort towards monitoring, enhancing PRPs and allocating budget for these programs to implement food safety management programs not only quality management programs. Effectiveness of implementation of PRPs should be assessed by verification activities on a planned routine basis. Therefore, verification activities should not be limited to one-time testing, since end product testing in general has several limitations. Food packaging companies should take into consideration within their scope the effect of distribution and various points in the supply chain especially when their product is being sold at retail markets. Hygienic

status should be maintained where proper wrapping and sealing of products should be carried to prevent contamination along the route before it reaches the consumer. Food packaging hygienic status has a great impact on the quality and safety of food especially when used without further sterilization for temperature sensitive food products. Our study was conducted on a small sample of factories due to confidentiality concerns; but it added to the body of science shedding light on the poor status of PRPs and the need to collect more data and assess compliance in both packaging and food companies. Studies should also assess status of exporters supplying food packaging worldwide. More studies should evaluate other testing parameters such as the presence of spores that withstand heat exerted during processing. Finally, clearer legislations and guidelines should be issued by national and international bodies for the variety of packaging material used; since guidelines are mainly present for chemical parameters such as chemical migration. Guidelines should include specific bacterial parameters to be tested, testing method, cut-off points for acceptability, and implementation of best practices for food packaging companies.

APPENDIX

Audit Checklist

N/A (score 0), NO (score 0), PARTIAL (score 1), and YES (score 2)

Clause	Score of Fulfilling Audit Criteria				
4.2 Layout and workspace	**Average Score (4.2):**				
4.2.1 General requirements	Average Score (4.2.1):				Reason
Internal layouts shall be designed, constructed and maintained to facilitate good hygiene and manufacturing practices.	0	0	1	2	
The movement patterns of materials, as well as recycled material; products and people, and the layout of equipment shall be designed to protect against contamination sources and unintended mixing of materials or products and cross-contamination	0	0	1	2	
4.2.2 Internal design, layout and traffic patterns	Average Score (4.2.2):				Reason
Buildings shall provide sufficient space to allow a logical flow of materials, products and people through the production process.	0	0	1	2	
Openings intended for transfer of materials and products (e.g. transport hoses, conveyors) shall be designed to prevent entry of foreign matter and pests.	0	0	1	2	
4.2.3 Internal structures and fittings	Average Score (4.2.3):				
Walls and floors shall be washable or cleanable, as appropriate for the food safety hazards associated with the food packaging production.	0	0	1	2	
Standing water shall be prevented in areas where food safety may be impacted.	0	0	1	2	
Drains shall be trapped and covered.	0	0	1	2	
Ceilings and overhead fixtures shall be designed to prevent build-up of dirt and condensation and shall be accessible for inspection and cleaning.	0	0	1	2	

In areas where routine cleaning of overhead fixtures and structures is not feasible or practical, equipment shall be covered.	0	0	1	2	
External opening doors, windows, roof vents or fans in production and storage areas shall be closed or screened (e.g. insect screened, air curtains). ***NOTE:*** *External openings should be avoided wherever possible. Where this is not possible, keeping these openings closed is the preferred option.*	0	0	1	2	
4.2.4 Equipment	Average Score (4.2.4):				Reason
Equipment shall be designed and located to facilitate good hygiene and manufacturing practices and monitoring.	0	0	1	2	
Equipment shall be located to permit access for operation, cleaning and maintenance.	0	0	1	2	
4.2.5 Temporary/mobile structures	Average Score (4.2.5):				Reason
Temporary structures shall be designed, located and constructed to prevent pest harbourage and contamination.	0	0	1	2	
4.2.6 Storage	Average Score (4.2.6):				
Facilities used to store raw material, intermediates materials, chemicals or finished food packaging shall provide protection from dust, condensation, drains, waste and other sources of contamination.	0	0	1	2	
Internal storage areas shall be dry and well ventilated. Monitoring and control of temperature and humidity shall be applied where necessary.	0	0	1	2	
If raw material, intermediates materials, chemicals or finished food packaging are stored outside, measures shall be in place to manage contamination hazards.	0	0	1	2	
Storage areas shall be designed or arranged to allow segregation of raw materials, intermediate materials, chemicals and finished food packaging. Raw materials intermediate materials, chemicals and finished food packaging that are suitable for food contact shall be segregated from those that are not.	0	0	1	2	

All raw materials, intermediate materials, chemicals and finished food packaging shall be stored off the floor and with sufficient distance from the walls to allow inspection.	0	0	1	2	
Storage areas shall be designed to allow maintenance and cleaning and to prevent contamination and deterioration.	0	0	1	2	
Chemicals and other hazardous substances shall be, suitably labelled, secured in closed containers and used in accordance with manufacturer's instructions.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.3 Utilities	Average Score (4.3):				
4.3.1 General requirements	Average Score (4.3.1):				Reason
The provision and distribution routes for utilities to and around production and storage areas shall be designed to prevent contamination.	0	0	1	2	
4.3.2 Water supply	Average Score (4.3.2):				
The supply of water of a suitable quality shall be sufficient to meet the needs of the food packaging production process and not cause a food safety hazard.	0	0	1	2	
The food packaging manufacturing organization shall establish requirement for Water (including ice or steam) used for direct food packaging contact or cleaning and shall monitor accordingly.	0	0	1	2	
Non-potable water shall have a separate supply system, labelled, not connected to the potable water system and prevented from refluxing into the potable system.	0	0	1	2	
4.3.3 Air quality and ventilation	Average Score (4.3.3):				Reason
The food packaging manufacturing organization shall establish requirements for air used for direct food packaging contact and shall monitor accordingly.	0	0	1	2	
Suitable and sufficient ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odours.	0	0	1	2	
Room air supply quality shall be controlled to prevent airborne	0	0	1	2	

microbiological contamination.					
Ventilation systems shall be designed and constructed such that air does not flow from contaminated areas to clean areas.	0	0	1	2	
Ventilation systems shall be accessible for cleaning, filter changing and maintenance.	0	0	1	2	
4.3.4 Compressed air and other gases	Average Score (4.3.4):				Reason
Compressed air and other gas systems used in food packaging manufacturing shall be constructed and maintained so as to prevent contamination.	0	0	1	2	
The food packaging manufacturing organization shall establish requirement for gases used for direct food packaging contact (including those used for transporting, blowing or drying raw materials, intermediate materials, finished food packaging or equipment and shall monitor accordingly.	0	0	1	2	
Oil used for compressors shall be food grade wherever is a potential contamination	0	0	1	2	
Requirements for filtration, humidity (RH %) and microbiology shall be assessed. Control and monitoring measures shall be applied as determine by the assessment. ***NOTE*** *Filtration of the air should be as close to the point of use as is* *practicable.*	0	0	1	2	
4.3.5 Lighting	Average Score (4.3.5):				Reason
The lighting provided (natural or artificial) shall allow correct operation of the food packaging production process. ***NOTE*** *The intensity of the lighting should be appropriate to the nature of the operation.*	0	0	1	2	
Where there is a food safety hazard, light fixtures shall be protected to prevent contamination of raw materials, intermediates materials, chemicals, finished food packaging product and equipment in the case of breakages.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria

4.4 Waste	**Average Score (4.4):**				
4.4.1 General requirements	Average Score (4.4.1):				Reason
Systems shall be in place to identify, collect, remove and dispose of waste materials in a manner that prevents contamination.	0	0	1	2	
4.4.2 Waste Handling	Average Score (4.4.2):				
Containers for waste shall be: a)Emptied at appropriate frequencies b)Kept in adequate condition of cleanliness	0	0	1	2	
Waste shall be: a)Kept away from production & storage areas	0	0	1	2	
Bins and containers for non-production waste shall be: a) appropriately identified b) emptied regularly c) provided with lids (if necessary)	0	0	1	2	
Food packaging identified and designated as waste shall be disfigured or destroyed so that: a) trademarks or food ingredient information cannot be reused b) it cannot enter the supply chain again	0	0	1	2	
4.4.3 Drains and drainage	Average Score (4.4.3):				Reason
Drains shall be designed, located and constructed to prevent contamination.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria	
4.5 Equipment suitability, cleaning and maintenance	Average Score (4.5):	
4.5.1 General requirements	Average Score (4.5.1):	Reason

Equipment shall be designed to prevent contamination.	0	0	1	2	
Where relevant equipment used for irradiation processes shall meet the provision given in relevant food packaging specification.	0	0	1	2	
4.5.2 Hygienic design	Average Score (4.5.2):				
All parts of equipment coming into contact with the finished packaging shall be designed and constructed to facilitate cleaning and maintenance.	0	0	1	2	
Equipment shall meet established principles of hygienic design, including: a) smooth, accessible, cleanable food packaging contact surfaces; b) self-draining (for wet processes); b) use of construction materials compatible with intended food packaging, lubricant and cleaning or flushing agents.	0	0	1	2	
Piping and ductwork shall be cleanable and drainable, and shall not cause condensation or leakage that could contaminate food packaging.	0	0	1	2	
Valve connections and controls shall fail-safe to prevent contamination.	0	0	1	2	
Equipment components containing metals of known toxicity (e.g. mercury) shall not be allowed where they could compromise the food safety of the food packaging.	0	0	1	2	
4.5.3 Food Packaging contact surfaces	Average Score (4.5.3):				Reason
Food packaging contact surfaces shall be constructed from materials suitable for intended use, to prevent contamination.	0	0	1	2	
4.5.4 Maintenance	Average Score (4.5.4):				Reason
A system of planned maintenance shall be in place including all equipment	0	0	1	2	
Maintenance programs shall be systematically applied to minimize the potential for contamination of product by equipment.	0	0	1	2	

Priority shall be given for maintenance request where food safety is at risk	0	0	1	2	
Procedure is in place to remove any potential contamination from machinery and equipment after maintenance work.	0	0	1	2	
Maintenance personnel should follow prescribed procedure including: hygiene measures.	0	0	1	2	
Temporary engineering and modifications should be avoided, controlled, and should not become permanent. Effective measures should be implemented.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.6 Management of purchased materials and services	Average Score (4.6):				
4.6.1 General Requirements	Average Score (4.6.1):				Reason
Purchasing of materials, services, and subcontracted activities that impact food safety of food packaging shall be controlled such that the suppliers used have the capability to meet the specified requirements. ***NOTE:*** *Services may include (but are not limited to) third-party storage and rework by sub-contractors.*	0	0	1	2	
The organization shall set clear requirements to relevant outsourced processes. There shall be a written contract.	0	0	1	2	
4.6.2 Selection and management of suppliers	Average Score (4.6.2):				Reason
There shall be a documented procedure for the evaluation, approval and monitoring of suppliers in place to ensure compliance ,including: a) assessment of the supplier's ability to meet food safety s, requirements; b) description of how suppliers are assessed. The method used shall be justified by hazard assessment, including the potential food safety hazard to the food packaging. ***NOTE*** *Monitoring may include conformance to specifications, meeting CoA requirements and satisfactory audit outcomes.*	0	0	1	2	

4.6.3 Incoming raw materials	Average Score (4.6.3):				Reason
Loads on delivery vehicles shall be checked prior to, and during, unloading to verify that the food safety and the safety of raw material has been maintained during transit (e.g. seals are intact).	0	0	1	2	
Where temper evident seals are used, a verification process shall be in place to verify conformance to relevant customer or regulatory requirements	0	0	1	2	
Raw materials shall be inspected, tested or covered by CoA/DoC to verify conformance to specified requirements prior to acceptance or use. The method of verification shall be documented.	0	0	1	2	
Where incoming raw material is from a recycled source, measures shall be in place to verify food safety and traceability requirements are met to acceptance. ***NOTE*** *The inspection frequency and scope may be based on the hazard presented by the material and the risk assessment of the specific suppliers.*	0	0	1	2	
Raw materials that do not conform to relevant specifications shall be handled under a documented procedure which prevents their unintended use.	0	0	1	2	
Access points to bulk raw material receiving lines shall be identified, capped and secured. Discharge into such systems shall take place only after approval and verification of the raw materials received.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.7 Measures for prevention of contamination	Average Score (4.7):				
4.7.1 General requirements	Average Score (4.7.1):				Reason
Hazard analysis is carried out. Measures to prevent microbiological, physical, and chemical contamination shall be implemented.	0	0	1	2	
Where external product testing is required, it shall be carried out by an accredited test facility or one that follows international test facility guidelines. Where in-house testing is carried out, calibration of equipment shall be carried out against national standards or other accurate means.	0	0	1	2	
Mixing of raw or intermediate materials shall be prevented where hazards assessment reveals a food safety hazard.	0	0	1	2	

4.7.2 Microbiological contamination	Average Score (4.7.2):				Reason
Where there is a potential for microbiological contamination, measures shall be implemented to prevent or control the hazard.	0	0	1	2	
4.7.3 Physical contamination	Average Score (4.7.3):				Reason
Where glass and/or brittle material are used (for applications other that the food packaging production itself) in production or storage areas, periodic inspection requirements and defined procedures in case of breakage shall be put in place. ***NOTE:*** *Glass and brittle material (such as hard plastic components in equipment, sight glasses on storage vessels) should be avoided where possible.*	0	0	1	2	
In production and storage areas, surfaces intended to have contact with the product shall be free from splinters and any other source of contamination.	0	0	1	2	
A formal procedure for the use of sharps shall be in place. No sharp objects or loose tools shall be left in any place and on surfaces where product contamination can occur. The use of snap-off blade knives shall be forbidden.	0	0	1	2	
4.7.4 Chemical contamination	Average Score (4.7.4):				
Printed and coated materials shall be handled and stored in their intermediate and finished state in such a manner that transfer of substances to the food contact side via set-off or other mechanism is reduced to a safe level appropriate for these materials as defined by hazard assessment.	0	0	1	2	
Lubricant intended to come in contact with the product shall be of a grade suitable for the intended use.	0	0	1	2	
4.7.5 Chemical migration	Average Score (4.7.5):				Reason
Where a potential food safety hazard due to migration or other transfer mechanism, controls shall be implemented to prevent or control the hazard.	0	0	1	2	

Packing materials (e.g. pallets, films, containers) shall be made of suitable material and be clean and shall not contaminate the food packaging ***NOTE:*** *In some cases, treatment of pallets may be necessary* (such insecticides, fungicides, pesticides or other chemicals) *to meet regulatory or customer requirements.*	0	0	1	2	
4.7.6 Food allergen management	Average Score (4.7.6):				Reason
Where a potential for contamination from food allergens has been identified, controls shall be established, documented and implemented to prevent or control the hazard and to record and label accordingly.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.8 Cleaning	Average Score (4.8):				
4.8.1 General requirements	Average Score (4.8.1):				Reason
Cleaning programmes shall be established to maintain the production equipment and environment in a hygienic condition.	0	0	1	2	
4.8.2 Cleaning programmes	Average Score (4.8.2):				
Cleaning programmes shall specify at a minimum: a) areas and items of equipment to be cleaned; b) responsibility for the tasks specified; c) cleaning method(s) and frequency; d) Monitoring and verification arrangements for the cleaning.	0	0	1	2	
4.8.3 Cleaning agents and tools	Average Score (4.8.3):				Reason
Equipment shall be maintained in a condition that facilitates cleaning.	0	0	1	2	
Cleaning agents shall be clearly identified, stored separately and used only in accordance with the manufacturer's instructions.	0	0	1	2	
Cleaning tools shall be of hygienic design and maintained in a condition that does not present a potential source of	0	0	1	2	

contamination.					
4.8.4 Monitoring cleaning programme effectiveness	Average Score (4.8.4):				Reason
Cleaning programmes shall be monitored at frequencies specified by the food packaging manufacturing organization to ensure their continuing suitability and effectiveness.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.9 Pest Control	Average Score (4.9):				
4.9.1 General requirements	Average Score (4.9.1):				Reason
Appropriate measures shall be implemented to prevent creating an environment conducive to pest activity.	0	0	1	2	
4.9.2 Control programmes	Average Score (4.9.2):				
The food packaging manufacturing organization shall have a designated person to manage pest control activities and/or deal with appointed expert contractors.	0	0	1	2	
Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and, where necessary, personnel training requirements.	0	0	1	2	
Programmes shall include a list of chemicals that are approved for use in specified areas of the establishment	0	0	1	2	
4.9.3 Preventing access	Average Score (4.9.3):				Reason
Establishment shall be maintained in good condition.	0	0	1	2	
External doors, windows or ventilation openings shall be designed to prevent entry of pests. All external doors shall be kept in good condition and closed when not in use.	0	0	1	2	

Incoming and outgoing products and materials should be checked for presence of contaminants from rodents, flying and crawling insects, birds and other pests.	0	0	1	2	
4.9.4 Harbourage and infestations	Average Score (4.9.4):				Reason
Raw materials, intermediate and finished food packaging found to be infested shall be handled in such a way as to prevent contamination of other raw materials, intermediate materials, finished food packaging or the establishment.	0	0	1	2	
Potential pest harbourage (e.g. burrows, undergrowth, stored items) shall be removed.	0	0	1	2	
Where external space is used for storage, stored items shall be protected from weather and pest damage (e.g. bird droppings).	0	0	1	2	
4.9.5 Monitoring and detection	Average Score (4.9.5):				Reason
Pest monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained.	0	0	1	2	
Detectors and traps shall be designed and located so as to prevent contamination of raw materials, intermediate materials and finished food packaging and equipment.	0	0	1	2	
Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest.	0	0	1	2	
The detectors and traps shall be inspected at a frequency intended to identify new pest activity. The results of inspections shall be analysed to identify trends in pest activity.	0	0	1	2	
4.9.6 Eradication	Average Score (4.9.6):				Reason
Eradication measures shall be put in place immediately after evidence of infestation is reported.	0	0	1	2	
Pesticide use and application shall be restricted to trained personnel and shall be controlled to avoid food t safety hazards.	0	0	1	2	
Records of pesticide use shall be maintained to show the type, quantity and concentrations used; where, when and how applied, and the target pest.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.10 Personnel hygiene and facilities	Average Score (4.10):				
4.10.1 General requirements	Average Score (4.10.1):				Reason
Requirements for personal hygiene and behaviours proportional to the hazard posed to the food packaging shall be established and documented. All personnel, visitors and contractors shall be required to comply with the documented requirements.	0	0	1	2	
4.10.2 Personnel hygiene facilities and toilets	Average Score (4.10.2):				Reason
Personnel hygiene facilities shall be available to maintain the degree of personal hygiene required by the food packaging manufacturing organization. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.	0	0	1	2	
According to their size and complexity, food packaging manufacturing organization shall: a) provide adequate numbers, locations and means of washing, drying and, where required, sanitizing hands (including wash basins, supply of hot and cold or temperature controlled water, and soap and/or sanitizer); b) provide an adequate number of toilets facilities of hygienic design separated from production areas, each with hand washing and drying, and sanitizing facilities c) toilet and changing facilities shall be kept clean d) have adequate changing and storage facilities for personnel (working in production, packaging, and storage areas.	0	0	1	2	
Changing and storage facilities should be accessible without crossing the production and storage areas when coming from the outside NOTE: where for safety and the above should be done, it can be controlled by controlled or designated routes	0	0	1	2	
4.10.3 Staff canteens and designated eating and smoking areas	Average Score (4.10.3):				Reason
Staff canteens and designated areas for food storage and consumption shall be situated and appropriately managed to prevent contamination of production areas.	0	0	1	2	

All food, drinks and medicines should be stored in designated areas. Procedures should be in place to control the use of medicines to prevent product contamination	0	0	1	2	
Eating (confectionary, chewing gum, chewing tobacco), drinking other than water and smoking should be allowed in designated areas only. Where drinking of water is allowed it should be subject to control to prevent spillage and contamination	0	0	1	2	
These areas should be kept clean, appropriate and cleanable lidded containers should be used for disposal of waste.	0	0	1	2	
Adequate containers for smokers' waste should be provided	0	0	1	2	
4.10.4 Work wear and protective clothing	Average Score (4.10.4):				Reason
Personnel who work in, or enter into production or storage areas shall wear work clothing that is fit for purpose, clean and in good condition.	0	0	1	2	
Work clothing shall not be used for any other purpose and shall not be stored in the same locker as personal clothing	0	0	1	2	
Work clothing shall provide adequate coverage so that hair, perspiration and loose items cannot contaminate raw materials, intermediate materials, finished food packaging or equipment based on a food safety hazard assessment.	0	0	1	2	
Where gloves are used for packaging contact, they shall be clean and in good condition.	0	0	1	2	
Personal protective equipment, where required, shall be designed to prevent product contamination and shall be maintained in hygienic condition.	0	0	1	2	
4.10.5 Illness and injuries	Average Score (4.10.5):				
Personnel, visitors and contractors shall be required to report relevant infections, conditions or diseases in accordance with the food manufacturing organization's requirements.	0	0	1	2	
People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from handling food packaging. Medical screening procedure may be in place.	0	0	1	2	

Self-adhesive plasters shall not contaminate the product. They shall be differentiated from the product (e.g. by color)	0	0	1	2	
4.10.6 Personal cleanliness	Average Score (4.10.6):				Reason
Personnel who are working in production areas shall be required to wash their hands: a) before starting any food packaging handling activities; b) immediately after using the toilet, eating, smoking or drinking (other than water); c) Immediately after handling any potentially contaminated material. Note: Hand cleaning products suitable for food safety (e.g. odourless) should be used.	0	0	1	2	
Personnel shall be required to refrain from sneezing or coughing over raw materials, intermediates or finished food packaging. Spitting (expectorating) shall be prohibited.	0	0	1	2	
Fingernails shall be kept clean and trimmed.	0	0	1	2	
4.10.7 Personal behaviour	Average Score (4.10.7):				Reason
A documented policy shall describe the behaviours required of personnel in production and storage areas.	0	0	1	2	
The policy shall at a minimum cover: a) permissibility of smoking, drinking (other than water), eating and chewing in designated areas only; b) control measures to prevent hazards presented by permitted jewellery; ***NOTE*** *Permitted jewellery includes specific types of jewellery that may be worn by the personnel in processing and storage areas because of religious, ethnic, medical and cultural imperatives.* c) permissibility of having personal items, such as smoking materials and medicines, in designated areas only; d) prohibition of the use of nail polish, false nails and false eyelashes; e) Control measures to restrict writing implements or loose items in	0	0	1	2	

areas where they could contaminate raw materials, intermediate materials or finished food packaging. f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing; g) Prohibition of storage of food packaging contact tools in personal lockers.					

Clause	Score of Fulfilling Audit Criteria				
4.11 Rework	Average Score (4.11):				
4.11.1 General requirements	Average Score (4.11.1):				Reason
Rework shall be stored, handled and used in such a way that food safety performance of food packaging, quality, traceability and regulatory compliance are maintained.	0	0	1	2	
4.11.2 Storage, identification and traceability	Average Score (4.11.2):				Reason
Stored rework shall be segregated and protected against contamination.	0	0	1	2	
Rework shall be clearly identified and labelled to allow traceability. Traceability records for rework shall be maintained.	0	0	1	2	
The rework classification or the reason for rework designation shall be recorded (e.g. food packaging name, production date, shift, line of origin).	0	0	1	2	
4.11.3 Rework usage	Average Score (4.11.3):				Reason

Where rework is to be incorporated back into the production process, the acceptable quantity, type and conditions of rework use shall be specified. The method of addition, including any necessary pre-processing stages, shall be defined.	0	0	1	2	
Measures shall be in place to prevent rework processes allowing raw materials, intermediate materials or finished food packaging to be contaminated with materials not intended for food contact.	0	0	1	2	
Validation records shall be kept to demonstrate that conformance to regulatory and customer requirements are maintained by following the specific rework process.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.12 Withdrawal Procedures	Average Score (4.12):				
Systems shall be in place to ensure that products failing to meet required food safety standards can be identified, located and removed from all necessary points of the supply chain.	0	0	1	2	
System shall be recorded and tested at an appropriate frequency.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.13 Storage and transport	Average Score (4.13):				
4.13.1 General requirements	Average Score (4.13.1):				Reason
Raw materials, intermediate materials and finished food packaging shall be stored in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.	0	0	1	2	
Subcontracted storage areas shall fulfil the requirements of this TS.	0	0	1	2	
4.13.2 Warehousing requirements	Average Score (4.13.2):				Reason
Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by food packaging or storage specifications.	0	0	1	2	
Waste and chemicals (cleaning products, lubricants, and pesticides) shall be stored separately.	0	0	1	2	

Measures shall be in place (electronically or physically separated) to avoid non-conforming materials to be released and or delivered.	0	0	1	2	
Specified stock rotation systems should be in place.	0	0	1	2	
4.13.3 Vehicles, conveyances and containers	Average Score (4.13.3):				Reason
Vehicles, conveyances and containers shall be maintained in a state of repair, cleanliness and condition consistent with requirements given in relevant specifications and contracts.	0	0	1	2	
Vehicles, conveyances and containers shall provide protection against damage or contamination of the food packaging.	0	0	1	2	
Control of temperature and humidity shall be applied, recorded and accessible where required.	0	0	1	2	
Transport vehicles shall be checked before loading and unloading. Good usable condition, clean and free from foreign bodies, pests, and undesirable odour.	0	0	1	2	
Food packaging shall be protected from contamination during loading operations. Where required by the food packaging manufacturing organization, bulk containers shall be dedicated to a specified packaging material.	0	0	1	2	
Pallets shall be inspected before use. They shall be suitable for intended use and clean, free from foreign bodies, pests and undesirable odours. Pallets shall not contaminate raw materials, intermediate products and food packaging.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.14 Food packaging information and customer communication	Average Score (4.14)				Reason
The organization shall be able to demonstrate compliance with food safety requirements and agreed specifications.	0	0	1	2	
The organization shall obtain the information necessary to determine that the food packaging to be provided is suitable for the intended use and will meet the food safety requirements. In case of changes to the food packaging, the organization shall assess any implications for food safety and compliance.	0	0	1	2	

The organization shall provide and update food safety relevant information on product applicability and restrictions of use to its customers. NOTE: Information can be provided by labelling or other means, such as company websites and advertisements and may include storage, instructions applicable to the product.	0	0	1	2	
Where as part of the process food safety, information is provided on the food packaging, this information shall be complete, legible and controlled to prevent misprinting.	0	0	1	2	

Clause	Score of Fulfilling Audit Criteria				
4.15 Food defence and bioterrorism	Average Score (4.14)				Reason
Each food packaging manufacturing organization shall assess the risk posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures.	0	0	1	2	
A procedure shall be in place for management of security incidents. It may include but is not limited to: a) building and infrastructure design to prevent unauthorized entry b) reference checks for personnel; c) control of confidential information; d) security of storage and production areas; e) transport and distribution	0	0	1	2	
The security assessment shall be kept up to date.	0	0	1	2	
Personnel shall be trained in site security measures.	0	0	1	2	

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