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ESTABLISHMENT OF HACCP SYSTEM FOR RAW UNCLEAN EDIBLE BIRD'S NEST PROCESSING PLANT IN MALAYSIA

(Penubuhan Sistem HACCP untuk Loji Pemprosesan Sarang Burung Walet Mentah Belum Bersih di Malaysia)

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ABSTRACT

The focus of the study is on the establishment of HACCP system for raw unclean edible bird's nest (RUC EBN) processing plant in Malaysia. Exploratory hazard analysis was applied to examine and prognose the possible failure modes in processing of raw unclean EBN based on characteristics, purpose or the interaction of processes where the system affixed to. Critical Control Points were determined and administered in the Ishikawa diagram. Deployment of the Ishikawa diagram is to discover the major causes that lead to failure in the heat treatment process. Application of cause-and-effect diagram ascends us to promising results which validate and verify outcomes attained from Failure Mode and Effect Analysis (FMEA). Risk assessment outputs from FMEA and food safety hazard matrix were compared concurrently. FMEA is deployed as part of risk assessment in Hazard Analysis and Critical Control Point (HACCP) system of raw unclean edible bird's nest processing. Enrollment of FMEA within Food Safety Management System (FSMS) contribute to a more definite qualitative assessment where rapid preventive or corrective intercession is possible.

Keywords: edible bird's nest; HACCP; FMEA; hazard analysis

ABSTRAK

Fokus kajian adalah terhadap penubuhan sistem HACCP untuk loji pemprosesan sarang burung walet mentah belum bersih (RUC EBN) di Malaysia. Analisis bahaya penerokaan telah digunakan untuk memeriksa dan meramalkan kemungkinan mod kegagalan dalam pemprosesan EBN mentah yang tidak bersih berdasarkan ciri, tujuan atau interaksi sistem yang dilaksanakan padanya. Titik Kawalan Kritikal telah ditentukan dan dipantau menggunakan rajah Ishikawa. Penggunaan rajah Ishikawa adalah untuk mencari punca utama kegagalan dalam proses rawatan haba. Penggunaan gambar rajah sebab dan akibat membawa kita kepada keputusan yang mengesahkan hasil yang diperoleh daripada Mod Kegagalan dan Analisis Kesan (FMEA). Output penilaian risiko daripada FMEA dan matriks bahaya keselamatan makanan dibandingkan secara serentak. Kaedah FMEA digunakan sebagai sebahagian daripada penilaian risiko dalam sistem HACCP pemprosesan sarang burung mentah belum bersih. Maklumat FMEA dalam sistem pengurusan keselamatan makanan menyumbang kepada penilaian kualitatif yang lebih pasti yang mana perantaraan pencegahan atau pembetulan adalah serta-merta.

Kata kunci: sarang burung walet; HACCP; FMEA; analisis risiko

1. Introduction

Swiftlet species (*Aerodramus fuciphogus* & *Aerodramus maximus*) secrete saliva from the sublingual salivary gland during rearing and nesting which lead to the formation of edible bird's nest (EBN). Grading of EBN is connected to the location of nests being harvested, external characteristics (color, degree of feathers, size and shape) and cleanliness (Koon 2000). In terms of export, it can be categorized into three major groups which are raw clean EBN, raw unclean EBN and EBN products. Due to the advancement of science and technology, nutritional and therapeutic properties of EBN were verified. Anti-aging and anti-inflammatory properties were investigated by the means of UV induction and stimulation of receptors. Such effects advocated wound healing, bone strength improvement and boosting of antioxidant capacity. Potential benefits of EBN on alleviating metabolic disorders like insulin resistance, diet-associated hypercholesterolemia and hypertensive effect (Hou *et al.* 2015). Due to its biochemical and phytochemical components, EBN has an auspicious research potential.

In terms of production volume, Indonesia is currently the prime producer and exporter for both raw and processed EBN, followed by Thailand and Malaysia. Due to the expansion in swiftlet farming industry and difficulties in cave nest harvesting, the main supplies of EBN shift towards the purpose-built swiftlet birdhouses (Tan *et al.* 2018). Quality and quantity of cave nests is correlated to the environmental condition of the natural cave. Under man-made environment, surrounding hygiene is maintained and the harvesting process is effortless. Therefore, house nest is a preferable option for an EBN processing plant. Tremendous increase in the quantity of swiftlet farms leads to the increase in EBN processing plant (Kamaruddin *et al.* 2019). Although the quantity of swiftlet farms has mushroomed during the last decade, EBN processing has not encountered significant changes and technological improvement. Uphold of EBN quality still remains a challenge where it is highly vulnerable to processing conditions that subject it towards degradation.

Vital issue concerning RUC EBN processing is the outbreak of Highly Pathogenic Avian Influenza (H5N1) in Kelantan back in 2017 (Mohd Shahar 2017). Due to the sudden outbreak, temporary import restrictions were imposed by China's authority. Pricing of Malaysia EBN plummeted which affect the wholesale price of RUC EBN as well (Chua & Zukefli 2016). Impact of the H5N1 avian flu eruption was immense as it affected the nation's overall export volume as well (Mohd Shahar 2017). Avian influenza virus still possesses a compelling challenge to the poultry industry where the safety of the product creates tension and discomfort among consumers. Stephens and Spackman (2017) stated that avian influenza virus predominantly exists in wild birds which are capable of infecting the poultry and other bird species. Avian influenza virus reproduced in gastrointestinal and respiratory tract of birds and expelled through oral cavity or conjunctiva (Centers for Disease Control and Prevention 2005). Massive amounts of H5N1 virus are discharged through feces becoming a great concern for virus transmission and environmental contamination (Kurmi *et al.* 2013). Due to its airborne transmission capability, it is highly transmissible among the avian population and mostly infect human respiratory systems. Postharvest handling of RUC EBN requires inclusion of a heat treatment process as an approach to eliminate Highly Pathogenic Avian Influenza (H5N1). Since avian influenza is heat-labile, it will be degraded when subjected to heat treatment (Doyle *et al.* 2007). Numerous chemical and physical inactivation methods were proposed for controlling H5N1 viruses in food and the environment. Among all control measures method of virus inactivation, thermal inactivation found out to be effective against H5N1 virus (Swayne 2006).

In terms of risk assessment, both FMEA and HACCP share some resemblance in terms of the process flow and accountabilities in the quality system. As for the relationship with the total quality system, development of FMEA managed to reduce the non-conformance risk ranging from a product to process. HACCP only emphasizes the safety risk related to the food manufacturing process. In view of problem definition, HACCP interprets how the foods can be affected by biological, chemical and physical hazards whereas the FMEA analyzes the repercussions of product alteration. Jong *et al.* (2013) utilized fuzzy-based FMEA toward the EBN production processes typically in Borneo Island, computed outputs were used to identify issues during management of EBN processing.

Though, there is limited studies available for the development of HACCP system in the processing of edible bird's nest. Chen *et al.* (2018) analyzed the hazards of EBN by deployment of HACCP plan. Kurniawan *et al.* (2021) implemented HACCP as food safety assurance for EBN products in Indonesia supplied to China. Due to the variation in national standard on EBN requirements, HACCP design and approach for each enterprise might have a contrast. Hence, the aim of the study was to develop a comprehensive food safety management system for the processing of raw unclean EBN in Malaysia.

1.1. *Processing of edible bird's nest*

Due to the shifting of demand especially in the Chinese community, below par and substandard EBN penetrate the market. Illegitimate acts like dyeing and adulteration are prevalent among the distributors which bring impacts to the market and misled the consumers. Adulterated and counterfeit EBN often penetrate other nations by informal channels (Chok *et al.* 2021). Table 1 outlined the illegal treatments during EBN processing. Orange-reddish to brownish-red color EBN, also known as "Blood EBN" in which the Chinese community tend to believe that it contained higher nutritional value and quality. Due to the color resemblance, the selling price continued to soar. Shim and Lee (2018) insinuated that the formation of red color is mainly due to the mineral's absorption from the wall where the nests are affixed. Certain EBN processors opted to counterfeit the reddish color on EBN with atrocious approaches and this irresponsible action caused the sodium nitrate dilemma back in 2011 (But *et al.* 2013; Lee *et al.* 2017).

1.1.1. *Upstream sectors*

Swiftlets' reproduction corresponded to the environmental conditions such as humidity, temperature, food availability and lastly the strategic location. Thus, swiftlets are scattered in Southeast Asia regions (Indonesia, Malaysia, Thailand, Vietnam and et cetera). Food availability is one of the requirements for swiftlets' reproduction. During the rainy season where the food sources are plenty, swiftlet will become active in breeding and reproduce twice. Picking technique and behavior of farmers determine EBN quality, uncontrolled harvesting is detrimental to overall sustainability of swiftlet. As a commitment for ecological protection, cave nest harvesting is prohibited and it leads to emergence of house nests. Pest disturbance issue in swiftlet houses is an alarming concern for the farmers. Insects, cockroaches and rodents are the most common source of infestation but there is no significant difference between the swiftlet house location and pest disturbance (Yaacob *et al.* 2021). Proper pest management within the swiftlet house capable of assuring the quality of EBN harvested. Till now, most of the swiftlet houses still do not exercise appropriate ranching practice as stipulated in the guideline. Good ranching practices should include the following program:

- EBN swiftlet houses varieties and security
- Ranching system
- Guano disposition method and treatment
- Pest control program
- Cleaning and maintenance plan

- Odor control scheme
- Disease control and management (Biosecurity)

Based on the research by Munirah *et al.* (2019), EBN entrepreneurs were suggested to implement ranching practices in the following conditions:

- Single lot building
- Single ranching system
- Frequency of cleaning and maintenance (At least once in every 3 months)
- Collection and compost of guano
- Application of aroma for swiftlet attraction
- Regular training on swiftlet disease management

Environmental factors might influence the swiftlet development as well. Certain parameters shall be abided to for swiftlet houses. To ensure sustained success of swiftlet houses, environmental factors should be monitored and assessed consistently. By maintaining the environmental factors, it resembled their natural habitat and the chances of swiftlet to adapt is higher.

1.1.2. *Midstream sectors*

Midstream sector emphasized on primary processing of EBN. EBN shall undergo certain processing before consumption. Based on Krabeethong *et al.* (2021), midstream sector should focus on following aspects:

- EBN-processing know-how
- Labor requirement and management
- Transportation
- Customer needs

Undoubtedly EBN processing is labor intensive that paired with inconsistency and human error and complication particularly in cleanliness diagnosis. Gwee *et al.* (2019) developed a systematic impurities ramification by the involvement of detection algorithm and automation based on the illumination aspect. Processing steps of EBN are tedious and hectic. In order to maximize the profit at low cost, lots of illicit approaches are introduced. Those adulteration issues serve food safety concerns for both consumers and the industry development.

Table 1: Felonious conduct during EBN processing

Illegal Act	**Purpose**
Removal of feathers by chemicals	Minimize the cost of labor
Bleaching	Embellish the appearance (Bright and Thick)
Water Spraying	Weight increment
Red Dye	Construct red EBN

1.1.3. *Downstream sectors*

Downstream sectors mainly emphasis on the diversification and development of ready-to-eat products. Based on Krabeethong *et al.* (2021), downstream sector should emphasize on following aspects (Distributors, Products, Customer needs). Typically, processed products ended up in different forms (candy, jelly, tablet and liquid). Inclusion of ginseng, goji berries, hawthorn and other nutritional-dense components are added value to EBN products (Lai *et al.* 2016).

Incorporation of biotechnology approach namely the extraction and enzymatic hydrolysis enable us to retrieve certain nutritive constituents from EBN. The correct combination of enzyme and hydrolysis methods facilitate the extraction of active ingredients in which the utilization of EBN is to the maximal (Wong *et al.* 2018; Fan *et al.* 2015). It is noticeable that the operators from upstream, midstream and downstream remain unchanged in which they are responsible for the entire supply chain of EBN.

1.1.4. *Industry actuality*

For the last decades, EBN was processed in an unhygienic environment with improper building construction which triggered the adulteration issue. Techniques used in processing plant establishment remain unchanged till now (Tan *et al.* 2018). Based on the observation on EBN cleaning processes, the majority adopted the piecemeal approach in the establishment of processing facilities. Processing of EBN requires massive labor inclusiveness and the cleaning process is the most vital and exhaustive. Goh *et al.* (2017) proposed the utilization of K-Means segmentation in impurities detection on various shapes to ease the later cleaning process. Due to the spike of consumer awareness on EBN quality control and commitment of DVSM on Veterinary Health Mark (VHM) certification scheme, EBN for exportation is required to meet the quality requirements and criteria. Till now, maintenance and uphold of EBN quality still remain challenging. Multitude of quality improvement activities on EBN have been performed and reported in previous literature. EBN processing methods still remain primal and non-existence of technology.

Raw unclean EBN processing plant is often known as the midstream sector in which the operations involved some elements from upstream and downstream sectors. Swiftlet ranchers and harvesters are considered as the upstream sector while the value-added products from EBN are categorized under the downstream sector. Export of raw unclean EBN to Mainland China was first established in 2018 and the Department of Veterinary Service Malaysia (DVSM) was in the midpoint of magnifying quality control for EBN products. With reference to Standard Operating Procedure for Operational Raw Unclean Edible Bird's Nest Primary Processing Establishment Export to China, quality and physical requirements for each process step are determined (Department of Veterinary Services Malaysia 2018).

Outburst of Highly Pathogenic Avian Influenza (H5N1) back in 2004 highlighted the safety of cultivating edible bird's nests (Lim *et al.* 2012). In order to fulfil the export requirements, every EBN subjected to export to China should be equipped with a traceability system and absent from avian influenza. Quality of RUC EBN exported to China abides to the regulations by the Department of Veterinary Service Malaysia (DVSM). EBN must undergo a heat treatment process where the core temperature should be more than 70°C and hold for at least 3.5 seconds to get rid of avian influenza virus. Only EBN approved by DVSM is authenticated and eligible for export to China. EBN processing facilities must be audited and endorsed by Certification and Accreditation Administration of the People's Republic of China (CNCA). China authority enforced rigorous procedures for EBN quality assurance by pursuing the entire supply chain (Thorburn 2015).

2. Materials and Methods

Hazard analysis and CCP determination for raw unclean EBN processing plant were established on extensive review of previous literature data, standard requirements, books and verifiable reports. Acquisition of basic information related to raw unclean EBN was executed through field observation in the processing establishment. Comprehensive technical process of raw unclean EBN processing was extracted and assisted in formation of flowchart and hazard analysis. Subsequently, CCPs were determined. Critical limits, monitoring steps, corrective measures, record, documentation and verification procedures were abided by relevant government regulations and industry standards. Decision tree analysis, a concise visual-based approach was implemented for CCPs identification. Decision tree analysis for sensitive raw materials and process steps were referred to MS 1480:2019 - Food safety according to the HACCP system (Second revision). Coverage of HACCP starting from raw materials received till the distribution stage.

2.1. *HACCP development and application*

Prerequisite programs (PRPs) such as good manufacturing practice (GMP) and cleaning and sanitation activities shall be established and maintained to fulfill the fundamental requirement of processing plant hygiene conditions. Proper implementation of PRPs enables more efficient control and management of the HACCP system (Wallace & Williams 2001). Preliminary procedures for HACCP application will not be discussed in detail in the study. Staff involvement and management commitment toward the HACCP objectives are critical. Buildup of the HACCP team should be multidisciplinary as the quality issues are not restricted to food only, peripherals contribute a large portion as well. Diversity of the HACCP team managed to deal with the issue during creating and implementing the HACCP plan. Personnel who are responsible for daily activities monitoring should be part of the team, they may deliver valuable data on current process limitations, inclusion develop a sense of allegiance. Continuous training on GMP and HACCP to ensure that the employees are updated to the latest revision. Product descriptions are defined by the HACCP team along with the process flowchart. Flowchart serves as the basis for the later hazard identification phase. Wallace and Williams (2001) revealed that all these elemental conditions shall be fulfilled before proceeding to the actual application phase of HACCP.

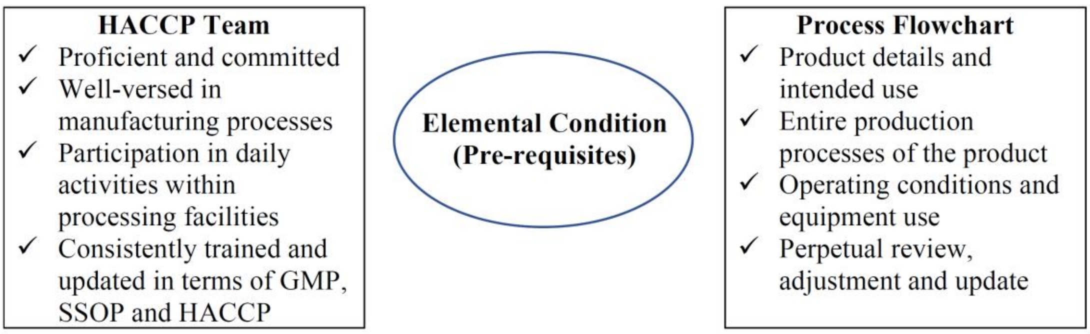

Figure 1: Pre-requisite program of HACCP (Wallace & William 2001)

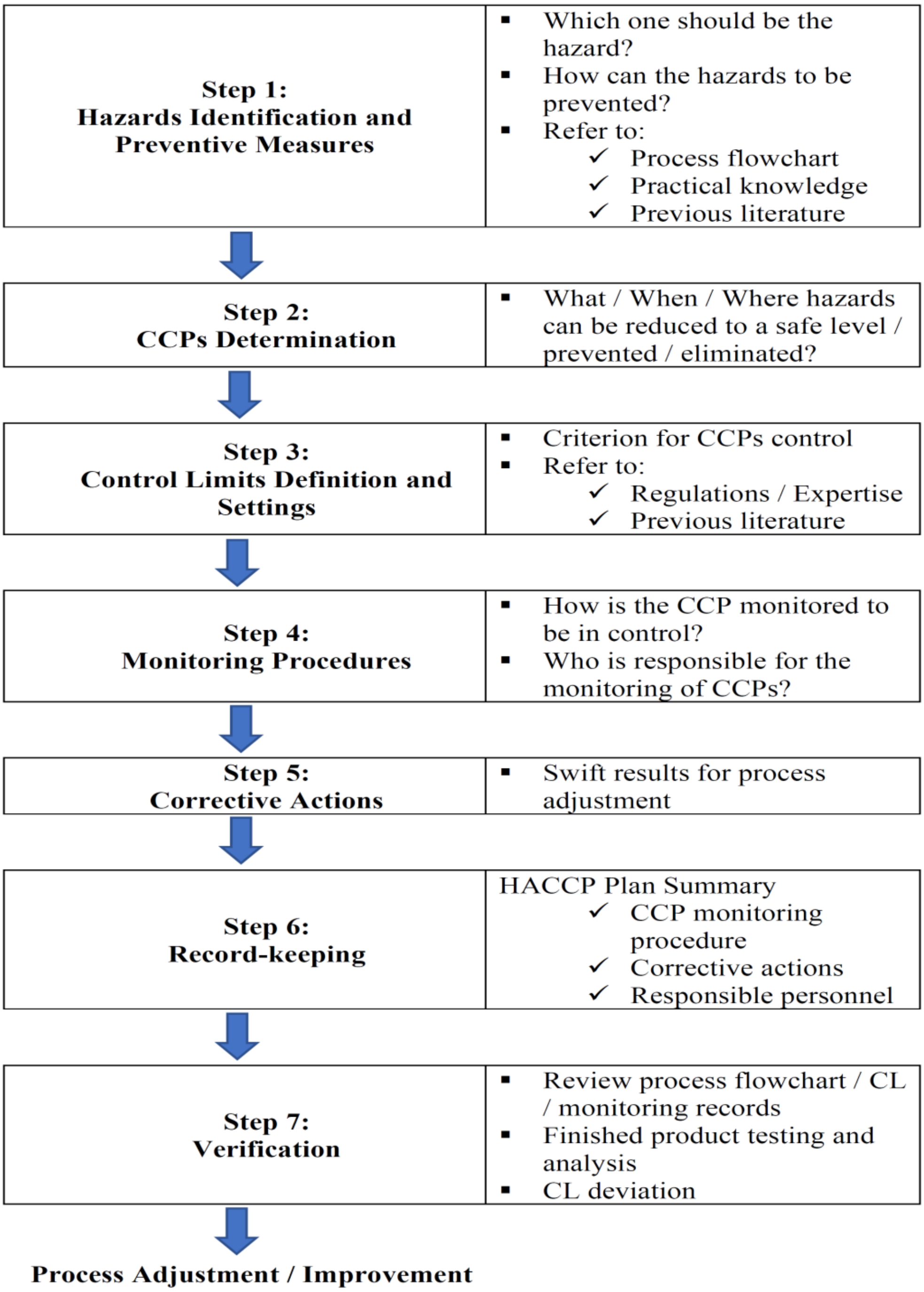

Figure 2: HACCP development and application flow (Cusato *et al.* 2012)

2.2. *FMEA (Failure mode and effect analysis)*

Failure, Mode and Effects Analysis is suggested as it aids in risk categorization by SOD factors. To be exact, it is the severity (S) factor, occurrence (O) probability and detection (D) probability of the heat sterilization process at risk. FMEA contemplates all the details incorporated in a system or process. Analysis is performed based on the historical information for homogenous items, including how each component and element might fail to attain the planned function. Deployment of FMEA in FSMS for the processing of raw unclean edible bird's nest have been phased, perceiving the setting of the following flow stages:

(1) Flow diagram
(2) Identify and describe each step in the process flow
(3) Identify and assess potential hazards of non-conformities in term of physical, chemical and biological hazards
(4) Pinpointing the root causes that led to the emersion of dangers
(5) Discover the probability of occurrence for each hazard category (O), determining the severity of the hazard occurrence to the consumer (S), establishing the probability of detection of hazards (D); Compute the Critical Index (RPN)
(6) Establishing critical control points (CCP) and HACCP plan
(7) For RPN > 100, corrective action shall be established for the particular category with the aim to attenuate the RPN.

Table 2: FMEA and corrective action deployment (Arvanitoyannis & Varzakas 2008)

Processing Stage	Hazards	Surveillance Activity	S	O	D	RPN	Corrective Action	S'	O'	D'	RPN'
CCPs											
OPRPs											

3. Results and Discussion

3.1. *Flow diagram analysis*

Design of processing flow is vital as the production procedure is referred to it for its function. Verification of process flowchart is performed by evaluating the production processes and coordination to authenticate the precision of arranged process flowchart. Adjustment and amendment are necessary if the actual condition is not reflected. On-site confirmation entailed designated personnel that is familiar with processing environment and operational procedure. Relevant documentations are reviewed during field assessment (Motarjemi 2000). Quality standards of raw unclean EBN is based on Standard Operating Procedure for Operational of Raw-Unclean Edible-Birdnest Primary Processing Establishment Export to China Annex B. Corlett (1998) addressed that upon the completion of 5 preliminary steps, it is followed by 7 principles of HACCP. Overall flow diagram of raw unclean EBN processing is outlined in Figure 2 including raw material receiving, sorting and grading, raw materials chill storage, pre-cleaning, drying, water-spraying, heat treatment, cooling, moisture checking, UV sterilization of primary packaging, primary packing, labelling, finished good chill storage, secondary packing, UV sterilization of secondary packaging and lastly distribution.

Process flowchart include the receiving of potable water and packaging materials, a more comprehensive review of the food safety management system. Receiving of raw unclean EBN is the first step of the flowchart, the EBN are harvested from the swiftlet farm at designated areas. During harvesting, usage of taping knife and swiftlet corners mirror ease the entire harvesting process. Upon collection of harvested EBN from the swiftlet farm, it is delivered to the processing establishment for further processing. Price of EBN is maneuvered by the grading and cleanliness, certain farmers will segregate the EBN based on predetermined grading specifications. Top-notch EBN will be sold with higher price while the inferior quality EBN is mixed with other lower specification product and eventually sold in lump sum basis. Incoming EBN mostly in lump sum basis, therefore the preliminary QC check is mandatory to uphold the quality of incoming raw materials. Preliminary QC check emphasized on the following parameters (grade, color, impurities, moisture content and absence of mold). In particular, location of swiftlet farms mostly situated in rural area, the EBN are embedded in either a PE plastic bag or polystyrene foam box. Transportation to the processing facilities is of ambient temperature. Due to the fragility of EBN, swiftlet farmer will spray additional water ahead of delivery in order to soften the EBN and minimize the cracking probability. Thus, sampling control at receiving stage is necessary. Next step is sorting and grading of EBN. This stage enables us to identify the amount of EBN received and aid in categorizing the EBN into respective specifications. Degree of differentiation of sorting and grading guideline among the EBN processing facilities are high but it does share a common attribute at its fundamentals. For all EBN processing establishments, each of them equipped with a unique batch number for traceability purpose. In common, the batch number or code include supplier's information, product specification, production date, lot number and et cetera. No restrictions are imposed on the formatting of traceability code as long as the processing plant capable to display the ability to track the production processes from any steps. Compliance with GMP practices and hygiene principles are significant to avoid for unsolicited changes in terms of product safety and quality. To minimize the possibility of cross-contamination, full-body ESD smock, glove, skull-cap and covered shoes shall be equipped at all time inside the production area. Followed by the chill storage of raw materials, sorted and graded EBN are subjected to chill storage temperature (< 4 °C).

Table 3: Specifications for raw unclean EBN (Department of Veterinary Malaysia 2018)

Category	Criterion	Tolerance level	Test Methods
Microbiology	*Escherichia coli*	≤ 1.0 x 10^2 cfu / g	Bacteriology Analytical Manual method or equivalent technique
	Salmonella Enteritidis	Not Detected	
	Salmonella Typhimurium		
	Salmonella Gallinarum		
	Coagulase +ve *Staphylococcus aureus*	≤ 2.5 x 10^3 cfu / g	
	Listeria monocytogenes	Not Detected	
Heavy Metals	Lead (Pb)	≤ 2 mg / kg	AOAC Atomic Absorption Spectrophotometer or equivalent
	Arsenic (As)	≤ 1 mg / kg	
	Mercury (Hg)	≤ 1 mg / kg	
	Cadmium (Cd)	≤ 1 mg / kg	
Foreign Matters	Paint, Wood, Twig, Cement, Sand, Soil, Dead nestling	Reasonably clean	Organoleptic approach

Regular conduct of hygiene training or seminar to strengthen the worker's understandings on the hygiene during food handling. Pre-cleaning process of EBN is labor-intensive, attention should be diverted to the scrutiny of stringent hygiene regulations. Cleaning tools, water sprayer and containers are provided for each operator where the pre-cleaning process shall remove primary feathers, paint, wood, feces, soil and other gross impurities with provided tools. All of the EBN are water-sprayed using potable, well-filtered water for softening purpose. Source of water utilized in the production must be potable and well-filtered to remove possible harmful microorganisms and complied to the requirements (The 25th A Schedule of the Food Act 1983 – Sub regulation 394(1)). Fragments and impurities obtained as by-product of pre-cleaning are segregated. EBN fragments has a resell value whereas the impurities are disposed along with municipal solid wastes. QC check is conducted at pre-cleaning step and the QC parameters are more of a visual approach. Experience, competency and precision are in demand for QC monitoring. Later, pre-cleaned EBN is subjected to drying step. Drying phase is determined as second OPRP. During the drying stage, it is divided into 3 scenarios:

- EBN with moisture content < 15 %
- EBN within desirable moisture content range (15 - 25 %)
- EBN with moisture content > 25 %

EBN are placed on the tray and inserted into drying rack for conventional air drying. Drying duration is set at 15 minutes for each tray. One tray of EBN represent one lot. Moisture content is checked after drying, 5 samples are selected from each tray to perform moisture check. If 1 out of the 5 samples fall in the scenario, different action is needed. For EBN with moisture content < 15 %, whole lot of EBN is proceed to water-spraying in later stage. Whole lot of EBN is sprayed with 3 - 4 % of filtered water in weight basis. Main objective of water-spraying is to prevent cracking of EBN during heat treatment in subsequent step. For EBN lot fall in the desirable moisture content range of 15 – 25 %, it will bypass the water-spraying step and proceed to heat treatment. For EBN lot with moisture content > 25 %, entire lot of EBN repeat the drying process for additional 15 minutes.
Next step in raw unclean processing plant is water-spraying stage. Water spraying process is the third OPRP for the processing line. Moisture content is one of the quality criteria for EBN, amount of water sprayed shall be monitored to prevent the outgrowth of mold. This stage was a conditional-step, the criteria was the moisture content of EBN after drying process. By dividing into three scenarios, processing establishment has better control over the moisture content as it was one of the significant quality indices for raw unclean EBN. Upon completion of water-spraying stage, the EBN proceed to heat treatment stage. This stage is a CCP with the aim to eliminate Highly Pathogenic Avian Influenza (H5N1) virus in EBN. Heat sterilization parameter required to be optimized to ensure that the core temperature of EBN achieve 70°C and above for at least 3.5 seconds during sterilization. Routine preventive maintenance in collusion with ongoing monitoring on production line and corrective actions are imposed uninterrupted in the event of deviation could minimize the product defect rate. Exemptions are given to product lot with defects in which the particular lot is exposed to heat sterilization again. Employee hygiene and control practices shall be maintained at all time to minimize the possibilities of cross-contamination. Microbial load and the existence of pathogenic microorganisms are the most concerning issues in raw products. Cleaning and sanitation of steam shrink tunnel contributed to the contamination as well, proper water discharge and exhaust system are necessary to prevent the accumulation of wastewater that may lead to pest infestation. The stage of heat treatment is followed by the stage of cooling. Heat-treated EBN should undergo cooling process. Relative temperature and humidity of the IPQC room are validated, EBN will be introduced to cooling at the spot where the cooling effect was maximized. Following that, moisture check is performed. This stage is CCP 2 because moisture content is one of the quality indicators for EBN. High moisture content created a medium of growth for the microorganism which is highly undesirable. For EBN lot

with moisture content > 25 %, whole lot of EBN is subjected to re-cooling. No water-spraying is allowed at cooling stage as the excessive spraying of potable water affect the final weight of the product.

Next step is the packing stage. Packing is performed in the air-conditioned room to inhibit or avoid the microbial growth. Primary packing used in the processing establishment is introduced to UV sterilization before the usage. UV disinfection has notable fungicidal and bactericidal properties but it is not recommended to irradiate with food, extreme oxidation might lead to food taste or discoloration changes. All primary packing used shall undergo decontamination by the means of UV, prolonged sterilization period is not advisable as it poses possibility of packaging rupture. Each packaged of EBN shall be labelled accordingly. For traceability and food safety consideration, labelling must be specific and with correct and clear statements. Labelling should be attached to the product till the distribution stage, if the label was broken in the midst of storage period, a replacement label will be attached. Vacuum-packaged EBN is transferred to finished good chill storage later. Vacuum-packaged EBN are subjected to chill storage temperature (< 4 °C). Single-packed vacuum-packaged EBN are packed together in corrugated carton boxes for secondary packing. If leakage was detected on primary packaging, the particular lot will not be processed. Repacking action is needed. Upon completion of secondary packing stage, each packaging undergoes UV disinfection for the second time. For primary packing, it will be UV sterilized before usage whereas for secondary packing, it is decontaminated after the packing process. It does not have direct contact with the food for both processes.

Lastly, distribution is the final stage of raw unclean processing line. No storage requirement is required for the transportation of EBN. Shelf-life study has been performed in ambient storage condition; the results has proven that EBN able to store at ambient storage condition for 24 months. Therefore, cold chain transportation is an option, another issue deal with cold chain transportation is the temperature settings. If the finished goods are exposed to chill storage during transportation, temperature fluctuation became a concern during the transfer of goods. Hygiene of vehicles and personnel handling the product are continuously monitored, inadequate sanitizing control and monitoring of distribution vehicle present an issue for distribution stage. Proper management and handling during distribution able to maintain the food safety and it is fulfilled by on-going training and assessment within the organization. Well-designed training program is beneficial for the management and the employee in the sense of the reduction of error or defect.

3.2. *Hazard analysis of raw material and packaging materials*

Hazard analysis for HACCP system is focused on three major categories which are biological, chemical and physical hazard. Assessment of raw material and packaging materials used in raw unclean EBN processing. A thorough list with potential hazards that might be the potential concern was generated. Hazard analysis for raw unclean EBN processing is accomplished in two phases which are raw materials and process steps. Harris (1999) stated that all forms of hazard able to penetrate a food at any point of processing.

Most commonly isolated bacteria from raw EBN are Bacillus sp. Bacillus cereus available in commercial EBN as well, it produced heat-resistant endospores that lead biofilm formation. Enterotoxins liberated by *Bacillus cereus* stimulate vomiting, nausea and diarrhea and cause secondary infections in immune-suppressed or normal personnel (Jeβberger *et al.* 2015). *Bacillus subtilis*, Gram-positive bacterium that predominantly appeared in soil and water. It is rarely associated with infection but breathing in of its derivatives might trigger allergic diseases (Cote *et al.* 2015). Aside than *Bacillus* spp., *Staphylococcus* spp. were isolated from the raw EBN. *Staphylococcus saprophyticus* are among the recognized bacterium that cause acute urinary tract infections after *Escherichia coli* that mainly detected in urine of young female (Ferreira *et al.* 2012). *S. aureus* in raw EBN is linked to the environment of swiftlet habitat. Total elimination of *S. aureus* in food manufacturing environment is critical but the process is challenging and grueling (Fetsch & Johler 2018).

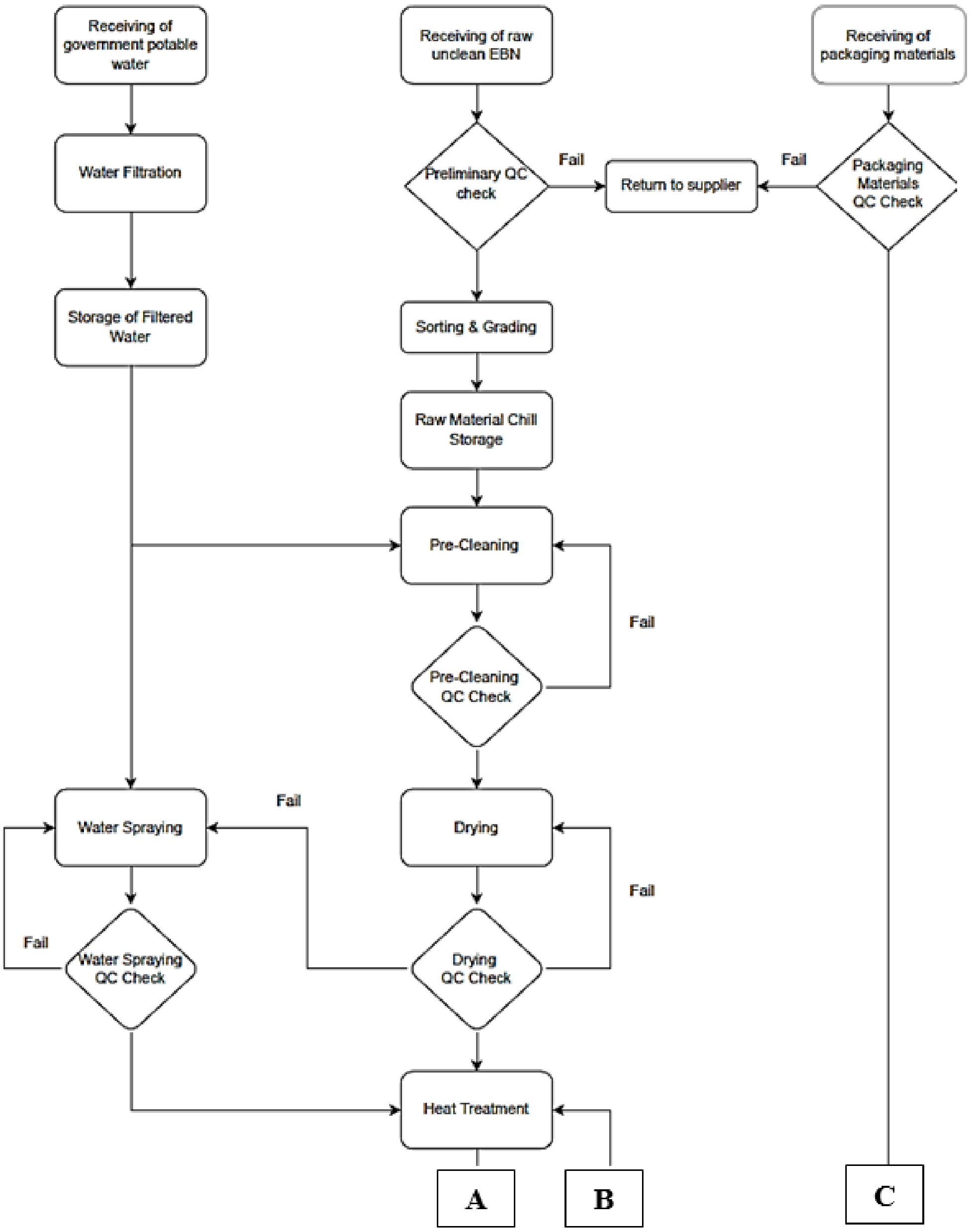

Figure 3 (*Continued*)

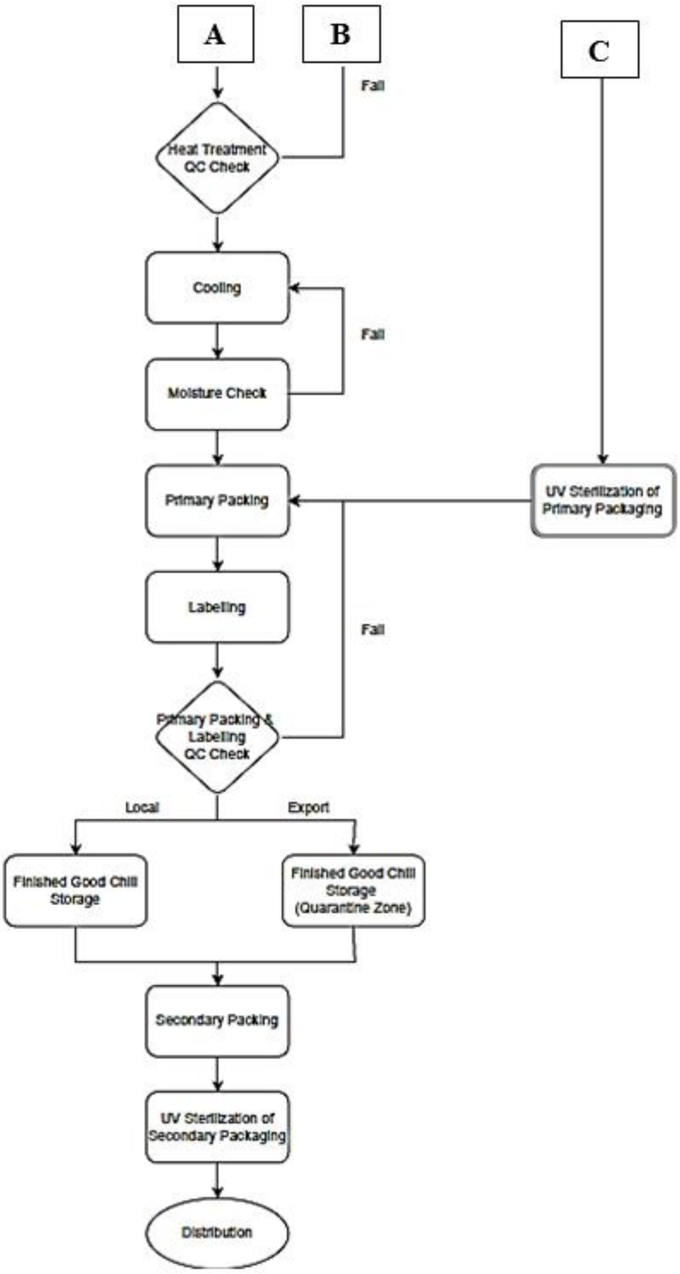

Figure 3: Process flowchart of raw unclean EBN processing

With reference to latest standard by DVSM, all raw unclean EBN should be absent of *Salmonella* spp., and *Listeria monocytogenes*. As for *Escherichia coli* and Coagulase-positive *Staphylococcus aureus* shall meet the tolerance level provided. Based on the latest findings, *Bacillus* sp. *Staphylococcus* sp. are among the most frequent airborne bacteria isolated from the swiftlets fecal sample (Lai *et al.* 2016). *Salmonella* sp., a pathogenic Gram-negative bacterium that predominantly found in animal goods, one of the most prevalent agents that cause foodborne disease. *Enterobacter* sp., coliform that linked to nosocomial disease. Fungal contamination is another challenge for EBN industry. Environmental fungi such as *Aspergillus* sp. is easily isolated from the deteriorated food. Mycotoxins produced are detrimental to human health in terms of safety during consumption and personnel who handled raw unclean EBNs (Yeo *et al.* 2021). Fungi are sturdy spoilage microorganism and presence of fungi penetrate food safety control settings of food manufacturing plant. Fungi possess rigorous survival characteristics and interchangeability between two forms (yeast, mold, combined form), therefore fungi existence in food is highly undesirable. For particular adulterants, the source of contamination remains unknown. Saliva, feathers, insects ingested by swiftlets, nest-associated microbes that resided on swiftlets or the nest. Contaminants or adulterants that introduced to commercial EBN become the possible source of infestation. Mites has been identified as pathogen that connected to allergy and anaphylaxis.

Jiang (2016) suggested that gamma radiation and microwave sterilization are effective in the reduction of yeast, mold, *Salmonella* and *E. coli* in EBN drink. Heat sterilization process enable effective eradication of mold and yeast, *E. coli*, *Salmonella* and *S. aureus* especially in beverages. Nest-associated bacteria is unable to be eliminate completely by any mean of processing. Selection of verified supplier and proper raw material inspection during receiving are indeed significant to minimize the possibility of contaminations. As for the packaging applied, integration and packaging materials properties should be examined, components of plastic packaging have the tendency to migrate into food if the usage conditions are abused. Storage for packaging should be in unsoiled and desiccated conditions to avoid the dust and impurities accumulation on the package itself that might possess a physical hazard. Hazard analysis is qualitative-based while the risk assessment is the quantitative process, quantification of risk assessment should be performed after hazard analysis is completed (Sperber 2001).

3.2.1. *Hazard determination and analysis of process step*

Biological, chemical and physical hazards for each process step are determined accordingly via hazard analysis. Each process step is connected to the quality of finished product, thus up from receiving till the distribution stage, hazard assessment shall be performed. Hazard analysis addressed the likelihood and severity of a particular incident or event towards the context of food safety. Probable contamination that occurred at any process step can be caused by mediocre hygienic status within production floor, unscheduled preventive maintenance, lack of provision on equipment further contaminates the product. Even with stringent processing method, the microorganisms in raw unclean EBN unable to eliminate entirely. HACCP team should have comprehensive understandings and knowledge on biological, chemical and physical hazards correlated to the product. Inability to determine the actual hazard of a process or product directly linked to safe consumption of food.

Table 4: Potential hazards in government potable water

1	2	3	4			5[a]	6[b]			
Raw Material / Packaging Materials	**Potential hazard state whether Biological (B), Chemical (C), Physical (P)**	**Justifications for inclusion or exclusion as hazard** **(In: Inclusion; Ex: Exclusion)**	**Is this a significant hazard?**			**What measures can be applied to control these significant hazards?**	**Is this a raw material/packaging**			
			Severity	**Likelihood**	**Y/N**		**Q1**	**Q2**	**Q3**	**Y/N**
Government Potable Water	**Biological** Survival of: *Clostridium perfringens* *E. coli* Coliform *Enterococcus* spp. *Vibrio* spp.	Ex: Water treatment is performed by Government or agencies according to MOH potable water standards	2	D	No	* Potable water received from local authority undergo stringent treatment procedure in order to meet the requirements as stated in Food Act 1983. * Water used in the processing plant will be collected for lab sampling annually for monitoring purpose.	-	-	-	-
	Chemical Excessive chlorine	Ex: Unlikely to cause a concern as potable water derived from government authority has been chlorinated.	4	D	No	* Receiving potable water is treated and filtered by filter with 250 microns and followed by UV disinfection * The filtration system is monitored and maintained on monthly basis. * Routine monitoring on the color and turbidity of filtered water used	-	-	-	-
	Physical Non-removal of residual soil, sand and other large particulate matters	In: Possible to be a concern as the incoming water supply from local authority is turbid and cloudy.	4	C	No		-	-	-	-

a. Significant hazards controlled under PRP's need to be indicated in the worksheet.
b. Q is based on Raw Material Decision Tree.

Table 5: Potential hazards in raw unclean edible bird's nest

1	2	3	4			5[a]	6[b]			
Raw Material / Packaging Materials	**Potential hazard state whether Biological (B), Chemical (C), Physical (P)**	**Justifications for inclusion or exclusion as hazard** **(In: Inclusion; Ex: Exclusion)**	**Is this a significant hazard?**			**What measures can be applied to control these significant hazards?**	**Is this a raw material/packaging material a sensitive material?**			
			Severity	**Likelihood**	**Y/N**		**Q1**	**Q2**	**Q3**	**Y/N**
Raw Unclean Edible Bird's Nest	**Biological** *E. coli* *Staphylococcus aureus* *Listeria monocytogenes* *Salmonella* Enteritidis *Salmonella* Typhimurium *Salmonella* Gallinarum Highly Avian Influenza Yeast and Mold	In: Nature raw unclean EBN that contaminated by droppings and environmental conditions.	2	D	No	* All raw material supplier has valid premise ID registered under DVS * Only receive raw unclean EBN from approved suppliers * Practice of Good Animal Husbandry Practice (GAHP) in the premise * Routine vendor assessment for raw material suppliers	-	-	-	-
	Chemical Excessive nitrite level	In: Natural EBN will have high nitrite content.	3	D	No	* RUCBN will undergo pre-cleaning, heat treatment process in later steps to reduce the nitrate level of RUCBN	-	-	-	-
	Physical Visible filth, feathers, dust, hair, twig, wood and paint residue	In: Nature EBN is contaminated with feathers, dirt, wood and paint residues.	4	D	No	* Visual & QC check on the hygiene of RUCBN and delivery transport * Visual inspection on the cleanliness of carrier container and container integrity of RUCBN	-	-	-	-

a. Significant hazards controlled under PRP's need to be indicated in the worksheet.
b. Q is based on Raw Material Decision Tree.

Table 6: Potential hazards in packaging materials

1	2	3	4			5[a]	6[b]			
Raw Material / Packaging Materials	**Potential hazard state whether Biological (B), Chemical (C), Physical (P)**	**Justifications for inclusion or exclusion as hazard** **(In: Inclusion; Ex: Exclusion)**	**Is this a significant hazard?**			**What measures can be applied to control these significant hazards?**	**Is this a raw material/packaging material a sensitive material?**			
			Severity	**Likelihood**	**Y/N**		**Q1**	**Q2**	**Q3**	**Y/N**
Packaging Materials (Primary & Secondary Packaging)	**Biological** Presence of mold and yeast	Ex: Not reasonably likely to occur as the packaging materials are purchased from established and approved supplier.	5	E	No	* Only purchase and receive packaging materials from approved supplier * Assess the supplier performance annually * Check the specification sheet of the packaging materials	-	-	-	-
	Chemical Non-food grade packaging materials	Ex: Not reasonably as all the incoming packaging materials shall declared as "food-grade" and non-food grade packaging materials are not accepted.	5	D	No	* QC check during receiving of packaging materials	-	-	-	-
	Physical Broken packaging, cartons & presence of dust & pest	Ex: Visual inspection upon receiving of damaged carton or presence of pest infestation. All incoming packaging are wrapped and secured.	4	D	No		-	-	-	-

a. Significant hazards controlled under PRP's need to be indicated in the worksheet.
b. Q is based on Raw Material Decision Tree.

Table 7: Questions used for CCP determination based on hazard analysis

1	2	3	4	5	6	7
Processing Steps	**Determination of Hazards**	**Are there control measure(s) for the significant hazard? (Yes/X)**	**Is this step specifically designed to eliminate or reduce the likely occurrence of hazard to an acceptable level? (Yes/X)**	**Could contamination with identified hazard(s) or could this increase to unacceptable levels? (Yes/X)**	**Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to acceptable levels?**	**Is this step a critical control point? (Yes/X)**
Receiving of government potable water	**Biological** Survival of *Clostridium perfringens* *E. coli* Coliform *Enterococcus* spp. *Vibrio* spp.	YES	X	YES	X	X
	Chemical Excessive chlorine	YES	X	YES	X	
	Physical Non-removal of residual soil, sand and other large particulate matters	YES	X	YES	X	

Table 7 (*Continued*)

Receiving of raw unclean EBN	**Biological** *E. coli* *Staphylococcus aureus* *Listeria monocytogenes* *Salmonella* Enteritidis *Salmonella* Typhimurium *Salmonella* Gallinarum Highly Avian Influenza Yeast and Mold	YES	X	YES	X	X
	Chemical Contamination by hand sanitizer, hand soap & cleaning compounds residue	X	X	X	YES	
	Physical Visible filth, feathers, dust, hair, twig, wood and paint residue	X	X	YES	YES	
Receiving of packaging materials	**Biological** Presence of mold and yeast	X	X	YES	YES	X
	Chemical Residue from cleaning compound and sanitizer	X	X	X	YES	
	Physical Broken packaging, cartons & presence of dust & pest	X	X	YES	YES	

Table 7 (*Continued*)

Water Filtration	**Biological** Survival of: *Clostridium perfringens* *E. coli* Coliform *Enterococcus* spp. *Vibrio* spp.	**YES**	**X**	**YES**	**X**	**OPRP 1**
	Chemical Excess chlorine residue	YES	X	YES	X	
	Physical Accumulation of impurities in downstream processes	YES	X	YES	X	
Sorting and Grading	**Biological** *Bacillus* sp. *Staphylococcus* sp. *Pseudomonas* sp. *Enterobacter* sp.	YES	YES	X	X	X
	Chemical Residue from cleaning compounds and sanitizer	YES	YES	X	X	
	Physical Presence of dirt and wood contamination	YES	YES	X	X	

Table 7 (*Continued*)

Storage of government potable water	**Biological** Survival of: *Bacillus* sp. *Staphylococcus* sp. *E. coli* *Enterococcus* spp. *Listeria* spp.	YES	X	YES	X	X
	Chemical Contaminations from algal toxin, chemical treatment impurities	YES	X	YES	X	
	Physical Presence of pest dropping, iron rust, pipe and tank leakage	YES	X	YES	X	
Raw Material Chill Storage	**Biological** Growth of: *Bacillus* sp. *Staphylococcus* sp. *Clostridium* sp. *Enterococcus* spp.	YES	X	YES	X	X
	Chemical Residue from cleaning compound and sanitizer	YES	X	YES	X	
	Physical Pest infestation	YES	X	YES	X	
Ambient Storage of Packaging Materials	**Biological** Growth of mold	YES	X	YES	X	X
	Chemical Residue from cleaning compound & sanitizer	YES	X	YES	X	
	Physical Presence of dust, cobwebs & pest droppings	YES	X	YES	X	

Table 7 (*Continued*)

Pre-Cleaning	**Biological** Growth of: *Bacillus* sp. *Enterococcus* sp. *Staphylococcus* sp. *Paenibacillus* sp.	**YES**	**X**	**X**	**YES**	**X**
	Chemical Cleaning compound residue	YES	X	X	YES	
	Physical Presence of primary feathers, paint, wood, feces, twig,	YES	X	X	YES	
Drying	**Biological** Accumulation of: *Listeria* spp. *Staphylococcus* spp. Mold	YES	X	X	YES	OPRP 2
	Chemical Cleaning compound residue	YES	X	X	YES	
	Physical Presence of dust, cobwebs, pest droppings, metal fragments (broken pieces of drying fan)	YES	X	X	YES	
Water Spraying	**Biological** Outgrowth of: *E. coli* *Bacillus* sp. *Staphylococcus* sp. *Clostridium* sp. Yeast and mold	YES	YES	X	X	OPRP 3
	Chemical Residue from cleaning compounds and sanitizer	YES	YES	X	X	
	Physical Presence of dust, cobwebs, pest droppings	YES	YES	X	X	

Table 7 (*Continued*)

Heat Treatment	**Biological** Survival of microorganisms and High Pathogenic Avian Influenza (H5N1) virus	**YES**	**X**	**X**	**X**	**CCP 1**
	Chemical Residue from cleaning compounds, sanitizer, grease	**YES**	**X**	**X**	**X**	
	Physical Presence of dust, cobwebs, iron rust	**YES**	**X**	**X**	**X**	
Cooling	**Biological** Outgrowth of yeast and mold	**X**	**X**	**X**	**X**	X
	Chemical Residue from cleaning compounds, sanitizer	**X**	**X**	**X**	**X**	
	Physical Presence of dust, cobwebs, iron rust	**X**	**X**	**X**	**X**	
Moisture Check	**Biological** Outgrowth of yeast and mold	**YES**	**X**	**YES**	**X**	**CCP 2**
	Chemical Residue from cleaning compounds, sanitizer	**YES**	**X**	**YES**	**X**	
	Physical Presence of dust, cobwebs	**YES**	**X**	**YES**	**X**	

Table 7 (*Continued*)

Primary Packing	**Biological** Growth of: *Staphylococcus* spp. *E. coli* Coliforms *Bacillus* spp. *Enterococcus* spp.	X	X	YES	X	X
	Chemical Cleaning compound residue	X	X	YES	X	
	Physical Broken packaging and presence of dust and cobwebs	X	X	YES	X	
Labelling	**Biological** No identified hazard	X	X	YES	X	X
	Chemical Leakage of printer ink	X	X	YES	X	
	Physical No identified hazard	X	X	YES	X	
Finished Good Chill Storage	**Biological** Growth of: *Bacillus cereus* *Campylobacter jejuni* *Clostridium perfringens* Shiga-toxin producing *Escherichia coli* (O157:H7) *Listeria monocytogenes* Salmonella *spp*. *Staphylococcus aureus*	YES	X	YES	X	X
	Chemical Residue from cleaning compound and sanitizer	YES	X	YES	X	
	Physical Pest infestation	YES	X	YES	X	

Table 7 (*Continued*)

Quarantine	**Biological** Growth of: *Bacillus cereus* *Campylobacter jejuni* *Clostridium perfringens* Shiga-toxin producing *Escherichia coli* (O157:H7) *Listeria monocytogenes* Salmonella *spp*. *Staphylococcus aureus*	YES	X	YES	X	X
	Chemical Residue from cleaning compound and sanitizer	YES	X	YES	X	
	Physical No identified hazard	YES	X	YES	X	
Secondary Packing	**Biological** Growth of: *Staphylococcus* spp. *E. coli* Coliforms *Bacillus* spp. *Enterococcus* spp. Mold	X	X	YES	X	X
	Chemical No identified hazard	X	X	YES	X	
	Physical Broken packaging and presence of dust, cobwebs and pest droppings	X	X	YES	X	
Distribution	**Biological** Growth of: *Bacillus* sp. *Staphylococcus* sp. *Clostridium* sp. *Enterococcus* spp. due to leakage and moisture absorption from surrounding	**YES**	**X**	**YES**	**X**	**X**

Table 8: Hazard analysis of OPRPs and CCPs

Process Step	**Potential hazard state whether biological (B), chemical (C), physical (P)**	**Is this a significant hazard?**		
		Severity	**Likelihood**	**Yes / No**
Water Filtration **(OPRP 1)**	**Biological** Survival of *Clostridium perfringens*; *E. coli*; Coliform; *Enterococcus* spp.; *Vibrio* spp.	2	D	No
	Chemical Excess chlorine residue	3	D	No
	Physical Accumulation of impurities in downstream processes	3	C	No
Drying **(OPRP 2)**	**Biological** Accumulation of *Listeria* spp.; *Staphylococcus* spp.; Mold	3	B	No
	Chemical Residue from cleaning compounds and sanitizer	4	D	No
	Physical Presence of dust, cobwebs, pest droppings, metal fragments (broken pieces of drying rack or fan)	4	D	No
Water Spraying **(OPRP 3)**	**Biological** Outgrowth of *E. coli*; *Bacillus* sp.; *Staphylococcus* sp.; *Clostridium* sp.; Yeast and mold	3	D	No
	Chemical Residue from cleaning compounds and sanitizer	4	D	No
	Physical Presence of dust, cobwebs and pest droppings	4	D	No
Heat Treatment **(CCP 1)**	**Biological** Survival of microorganisms and High Pathogenic Avian Influenza (H5N1) virus	1	B	Yes
	Chemical Residue from cleaning compounds, sanitizer, grease	4	D	No
	Physical Presence of dust, cobwebs, iron rust	4	D	No
Moisture Check **(CCP 2)**	**Biological** Outgrowth of yeast and mold	2	B	Yes
	Chemical Residue from cleaning compounds, sanitizer	4	D	No
	Physical Presence of dust, cobwebs	4	D	No

3.3. *CCP, OPRP and critical limits establishment*

With reference to the outputs of hazard analysis, the raw unclean EBN production process consists of two CCPs and three OPRPs. Definition for PRP, OPRP and CCP are varied. Table 9 outlined the core difference of three control measures in terms of definition, risk monitoring and control.

CCPs are initiatives that prevent or eliminate the hazard level to a safe indicator. CCP are the fundamentals of the HACCP system as the entire commitment for the system is dedicated to these measures (Damikouka *et al.* 2017). Critical limit is the processing requirement that needs to be fulfilled at every corresponding control points. Till recent, HACCP system is adopted as a preventive-based food safety technique to identify, evaluate and monitor the potential hazards existing in the raw unclean EBN processing plant in Malaysia. Proposed CCPs were mainly contributed to indecent practices and handling throughout the processing steps; inadequate food hygiene knowledge and insufficient training provided by the Management. Decision tree is vital for CCP determination in assessing sensitive raw materials, packaging materials and process steps. Misunderstandings and oversight might have an impact on later CCP identification, increase of CCP within a food processing premises are prominent if it is under control (Mohd Bakri *et al.* 2017). Decision tree might not be fit for use for all scenarios, it required a combination of other approach and training should be provided. HACCP plan generated are complex and massive documentations and monitoring are required for each CCPs identified. Quantity of CCPs within a FSMS must be feasible, for instance a simple manufacturing process shall not have more than 50 CCPs which is ludicrous (Wallace & Williams 2011). Plentiful of CCPs within a system influence the daily monitoring and operational activities and it has been proven that too much CCPs might lead to failure of FSMS. Critical limits are the values to the extent of the hazards are controlled at CCP. Established limits revealed whether the hazards are within control or not. Selection of factors for critical limit are not restricted, parameters like temperature and dimensions were evaluated. Not all hazards are identified as CCP, hazards that can be controlled by PRPs often set as CP. Overall, in EBN processing, 2 CCPs and 3 OPRPs were identified.

3.3.1. *CCP 1 Heat treatment*

First CCP suggested was the heat treatment process. Operating heat treatment temperature should be maintained at 90°C, conveyor belt speed settings at low speed and the temperature probe shall be attached to the base of EBN for real-time monitoring. Based on DVSM, the core EBN temperature should be ≥ 70°C and retained at least 3.5 seconds. Inadequate heat sterilization may be insufficient to get rid of Highly Pathogenic Avian Influenza (H5N1) whereas extremely high temperature or extended duration heat treatment were not recommended due to the possibility of product deterioration.

3.3.2. *CCP 2 Moisture check*

Second CCP in raw unclean EBN processing plant was the moisture check step. Moisture check was corresponded to the previous cooling step. Thus, room temperature and relative humidity were strictly controlled and monitored. Facilities shall ensure that the moisture content of dried raw unclean EBN were less than 25 % as stipulated in Standard Operating Procedure for Operational of Raw-Unclean Edible Bird Nest Primary Processing Establishment Export to China. Main concern of beyond limit moisture content was the outgrowth of mold as it provides a suitable growth medium for microbes. Moisture content often used as the indicator for stability and EBN quality (Zainab *et al.* 2013).

Table 9: Comparisons of PRP, OPRP and CCP (Mortimore & Wallace 2013)

Control Measures	**Pre-requisite program (PRP)**	**Operational Pre-requisite Program (OPRP)**	**Critical Control Point (CCP)**
Definition / Scope	Focus on the safe production environment of food industry	PRP that responsible of the control of significant hazards Mainly used as the control for upstream processes from CCP	A point or procedure where the controls are applied to a food safety hazard by the means of reduction, eradication and elimination.
Hazards relation	Not specifically linked to any hazard	Explicit for particular hazards	
Examples	• Pest control • Cleaning and Sanitation • GMP	• Hand washing and sanitizing • Sanitation effectiveness • Temperature and relative humidity control	• Moisture content • Cooling • Heat sterilization
Criteria, monitoring and validation	• General and non-specific control measures • Validation is not necessary • Degree of hazard control is not intensified as CCP.	• Critical limit is not required. • Emphasis on reduce the likelihood of hazard exposure instead of targeting a specific hazard source by observable criteria	• Measurable critical limits shall be designed to monitor the CCP. • Validation shall be conducted.
Correction/ Corrective Actions	• Applied on deviated PRPs.	• Corrective actions focus on the process. • Correction may direct on the product.	• Predetermined corrections on the product • Corrective actions imposed on the process

Table 10: HACCP plan for CCP 1 (heat treatment)

1	2	3	Monitoring				8	9	10
Critical Control Point	**Significant Hazards**	**Critical Limits**	**4**	**5**	**6**	**7**	**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
Heat Treatment	**Biological** Survival of microorganisms and High Pathogenic Avian Influenza (H5N1) virus	RUC is steamed at ≥ 90°C for 11s (To ensure that the inner core of EBN achieve a minimum of 70 °C for 3.5s)	Heat treatment time	Belt speed of conveyor	Every lot (Once)	By competently trained designed personnel Or QA/QC personnel	<u>If steam shrink tunnel was not at least 90°C:</u> Repeat the pre-heating process of steam shrink tunnel to reach 90°C for 15 minutes Maintenance of the steam shrink tunnel to determine the cause of low temperature and fix the steam shrink tunnel so the temperature is at least 90°C before EBN are heat-treated Re-calibrate, re-validate steam shrink tunnel if necessary	Check the core temperature of EBN using temperature probe Re-validate the steam shrink tunnel Review of heat treatment monitoring record Review of calibration & maintenance report of steam shrink tunnel	Heat Treatment Monitoring Record Calibration report of steam shrink tunnel, temperature display and temperature probe data logger Maintenance record of steam shrink tunnel
			Temperature of heat treatment	Attach the temperature probe to the coldest spot of EBN and loaded in steam tunnel	Every lot (Once)				

Table 11: HACCP plan for CCP 2 (moisture check)

1	**2**	**3**	**Monitoring**				**8**	**9**	**10**
Critical Control Point	**Significant Hazards**	**Critical Limits**	**4**	**5**	**6**	**7**	**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
Moisture Check	**Biological** Outgrowth of mold	Moisture Content Range = 10-25%	EBN moisture content	Visual direct observation of moisture checks by moisture probe	Every lot (Randomly choose 5 pieces)	By competently trained designed personnel Or QA/QC personnel	Check the moisture content of EBN and repeat the cooling process Repeat cooling process until the EBN moisture content <25% is achieved Re-train personnel if found incompetent in checking the moisture content of EBN Re-calibrate or maintenance of the moisture probes and timer	Review of moisture content monitoring record Review of calibration report of moisture probe and timer Review of maintenance record of moisture probe and timer	Moisture Content Monitoring Record Calibration report of moisture probes and timer Maintenance record of moisture probe and timer

Table 12: HACCP plan for OPRP 1 (water filtration)

1	**2**	**3**	**Monitoring**				**8**	**9**
Process Step	**Potential Hazards**	**Operational Limit/Control Specification**	**4**	**5**	**6**	**7**	**Corrective Action**	**Records**
			What	**How**	**Frequency**	**Who**		
Water Filtration	**Biological** Survival of *Clostridium perfringens* *E. coli* Coliform *Enterococcus* spp. *Vibrio* spp. **Chemical** Excess chlorine residue **Physical** Accumulation of impurities in downstream processes	Size of filter = 250-micron UV disinfection wavelength = 253.7nm (No foreign matter and impurities found in filtered water)	Filter integrity and efficiency	Perform water flow test or Replacement of filter	Monthly	Maintenance officer	Replace filtration media. Upgrade water filter maintenance plan. Increase back washes frequency.	Microbiological / Chemical Analytical Report Premise & Equipment Maintenance Record

Table 13: HACCP plan for OPRP 2 (drying)

1	**2**	**3**	**Monitoring**				**8**	**9**
Process Step	**Potential Hazards**	**Operational Limit/Control Specification**	**4** **What**	**5** **How**	**6** **Frequency**	**7** **Who**	**Corrective Action**	**Records**
Water Filtration	**Biological** Accumulation of *Listeria* spp. *Staphylococcus* spp. Yeast and mold	Moisture content = 15-25% Duration: 15 minutes	Moisture content of EBN	Moisture probe	Every lot (Randomly choose 5 pieces)	By competently trained designed personnel or QA/QC personnel	Whole lot of EBN is subjected for re-drying if 1 out of 5 samples contain more than 25% of moisture content Monitor the temperature and humidity of drying room	Moisture Content Monitoring Record (Drying Section) Temperature and Relative Humidity Log Air Monitoring Test Report Calibration Register & Report
			Duration of EBN drying	Display Alarm Timer	Every lot			

Table 14: HACCP plan for OPRP 3 (water spraying)

1	2	3	Monitoring				8	9
Process Step	**Potential Hazards**	**Operational Limit/Control Specification**	**4** **What**	**5** **How**	**6** **Frequency**	**7** **Who**	**Corrective Action**	**Records**
Water Spraying	**Biological** Outgrowth of yeast and mold	Moisture content: 15-25% Amount of water sprayed: (30-40g/1000g of dry matter)	Moisture content of EBN	Moisture probe	Every lot (Randomly choose 5 pieces)	By competently trained designed personnel or QA/QC personnel	Ensure the EBN contain at least 15% of moisture to prevent cracking during heat treatment. Monitor the amount of water sprayed on EBN	Water Spraying Monitoring Record Calibration Register & Report
			Amount of water sprayed	Weighing Scale	Every lot			

3.4. *Establishment of monitoring procedures, corrective action measures and verification procedures*

Critical limits shall be established for each CCP, demonstration of monitoring procedure in HACCP system ensure every CCPs are satisfied continuously. In layman term, critical limits differentiate acceptability from the intolerable control measures where the limits should be established upon the criterion that distinguished the control measure. Monitoring procedure should contain the following details: sampling quantity, assessment method, frequency of assessment, personnel responsible for the inspection. Even with the existence of monitoring procedure, deviation will still occur from any CCPs. If the monitoring results displayed that the benchmark is not fulfilled, immediate and suitable corrective actions must be in place. Corrective measures are necessary to control the CCP back to the safe level. If the corrective actions are deemed to be ineffective, improvement shall be done to ensure consistent effectiveness. As safety is the main concern of HACCP system, any unregistered or unfit product should require further testing for safety evaluation. Process adjustment is necessary at the moment that the monitoring results demonstrate a shift in CCP control.

Frequency of monitoring should be adequate for non-continuous monitoring system. Swift implementation of corrective actions is needed to rectify the flaw process, physical measurement is more preferable than microbiological testing. Hasty physical assessment results reflect the control of food microbiological characteristic (Stamov 2019). Control and monitoring of measuring devices are critical, failure in maintenance, re-calibration and verification will lead to irreversible losses to the corporation. Only competent personnel are assigned for the adjustment and testing for variability purpose. Malfunction resulted from poor handling, storage and maintenance should be avoided (Kumar 2015). All available calibration and verification report shall be documented. In small and medium establishment, single individual should be competent to carry out the monitoring of control measures and capable of making decision when there is a deviation together with administration of corrective actions.

Stevenson and Bernard (1999) presented that verification procedure is necessary to check the HACCP plan effectiveness, verification activities include the methods, analysis, testing and assessment towards the monitoring systems. Validity of HACCP plan is scientifically and technically appraised during verification activities (Dalgic & Belibagli 2008). HACCP emphasis is on the quantification of risk, risk prediction and demonstrate relevant monitoring initiatives via accentuation on process control. For documentation part, details of hazard analysis and CCP identification content are included. All available procedures assist in verification of HACCP system in terms of control and maintenance. Internal verification is encouraged to conduct bi-annually where the external verification is performed by third party accreditation bodies. Large-scale food processing facilities will retain food samples till the end of respective shelf life or for the sake of future analysis as a consequence of investigation of safety and quality related issues.

3.5. *Risk determination*

Risk assessment and analysis contributed insightful information on the emerged risks, these details serve as a guideline during HACCP deployment. Food safety risks might be derived from the materials, environment and the food handlers. Hence, it enables up to explore for possible risks, based on the intended use of the food, the assessment of risk is varied. Due to differentiation in the definition of risk level, impact and doses, reaction plan for risk eradication is diversified. Not all causes are evaluated equally in terms of intensity of effect, the risk should be examined individually. However, a range of acceptable limit is established to pinpoint the safe level. Food safety hazards are illustrated as 3 major types: biological, chemical and physical. Low level of probable hazardous components is commonly appeared in feedstocks. As the intensity of toxin increases, reaction with environment the lethality of the particular toxins will escalate. This phenomenon prevails in viruses and parasites as well.

For crisis management, it can be classified into 4 phases which are prevention, reporting, investigation and lastly the root cause analysis. Magnitude and consequences of the event differentiate incident from crisis, poor handling of incident elevated to the crisis. Root cause analysis should not be confounded with the interrogation of primary cause, it is mainly utilized as the postmortem practice to discover the underlying factors that lead to the causes. Based on Reason (1997), latent failures debilitate the food safety management but probability of failures that lead to incident occurrence increase. Numerous incidents cause found out to be latent failures especially in petrochemical and food industries. Latent failures are further elaborated in later section.

HACCP system is considered dynamic as a single change within the HACCP plan will lead to different outcome. All changes applied to HACCP system shall be taken into the account, even a minor adjustment possess a hazard to the final product. Therefore, hazard analysis should be created in all-inclusive mode that cover all the essentials for risk assessment. HACCP plan imposed shall be maintained continuously. Failure in consistent review of HACCP plan might end up with disastrous food safety issues. Analysis of new hazards should be conducted before, during and after a process which satisfied the process-based approach. By gap analysis, HACCP team may unfold the new hazards and provide relevant training.

3.5.1. *Results of food safety hazard matrix*

Food safety risk management as one of the core activities in HACCP development. Modern perception of risk analysis is adequate to deal with more complicated and evolving food safety issues along with science-based approaches (Attrey 2017). Major concept of risk analysis is how should we examine, manage and correspond the risk in reflect to adoption of food safety policies and standards. Food safety hazard matrix is tested on the likelihood of an event occurrence against the severity of the hazard. Both degree of hazard likelihood and severity were categorized into 5 classes. Biological hazards are the most concerned for both CCPs. Heat treatment and moisture check prone to have fatality occurrence and serious illness if the biological hazards were appeared. As for the likelihood of hazard occurrence for biological hazards, it is known to occur or the hazards has happened before. CCP1 and CCP2 acquired a value less than 10 and this implied that the hazard exposure poses a significant food safety issue. Control measures are mandatory for hazard with value less than 10. However, range of values of 11 – 25, introduction of corrective actions was optional but highly recommended. For chemical and physical hazards, hazard severity was ranked at "4" which indicate that the existence of the hazards might induce customer complaints. Chemical and physical hazards were not expected to occur within processing establishment and it was given the indicator of "D". With the combination of "4" and "D", value of 21 was obtained that means the it is a non-significant food safety concern.

For OPRPs, mostly the hazards having severity score of 3 – 4 and classified as "C" and "D" for likelihood of event occurrence. The hazards are not expected to occur as it can generate customer complaint or recall. Main concern for water filtration is the biological hazards, pathogenic microorganism in unsafe water prone to pose the food safety concern in later processing. Value reflected has displayed that all forms of hazards are significant issues. Thus, peculiar monitoring and corrective action shall be established if deviation occurs.

3.5.2. *Results of FMEA*

Risk Probable Number (RPN) identified the risk priority of failure modes, where the RPN can be expressed as RPN = S x O x D; where S = Severity of the risk, O = Probability of occurrence for the risk of contamination, D = Probability of the event of risk being detected. In current study, FMEA was constructed for CCPs only and RPN was calculated for both CCPs. Potential hazards in terms of biological, chemical and physical and corrective actions were addressed in Table. New RPN (RPN') was counted after the corrective actions were implemented. Limits set for RPN was 120, if the RPN exceeded this figure, corrective action shall be administered. For CCP 1 heat treatment process, corrective measures should be imposed. Technically, growth of pathogens shall be reduced and eliminated as the existence of pathogenic microorganism possess risk to the EBNs. RPN for biological hazards surpassed the critical limits in which the corrective actions are demanded. More stringent supplier quality assessment; consistent review and update of heat treatment control plan and maintenance program; rigorous food hygiene program capable to return the RPN to a safe parameter. Such approach is applicable to the second CCP as well, if RPN went beyond the safe limit, necessary corrective measures shall be in place. Occurrence possibility and probability of detection of biological hazards decline drastically as a results of corrective actions implementation, RPN' fall below the critical limit. Severity of the hazards often not correlated with administration of corrective measures. Critical level for RPN depends on the nature of industry, life-threatening products will set a lower critical level to ensure the risks are minimized.

For OPRPs, mostly the hazards having RPN below critical limit of 120 but with proper implementation of corrective action, probability of occurrence and detection is likely to be reduced. RPN value compressed below 100 after the implementation of suggested corrective actions on the particular failure modes. Outputs from the study emphasis on the significance of assessing the risk in systematic approach.

Table 15: FMEA analysis and corrective actions implementation on OPRPs

Processing Step	Risk	Surveillance Activity	S	O	D	RPN	Corrective Action	S’	O’	D’	RPN’
Water Filtration (OPRP 1)	**Biological** Pathogenic Microorganisms	Preventive maintenance program of water filtration system	5	5	3	75	* Lab sampling on potable water * Routine monitoring on color and turbidity of filter water	5	4	3	60
	Chemical Excess chlorine residue		5	4	5	100		5	3	4	60
	Physical Accumulation of impurities in downstream processes		4	4	4	64		4	3	3	36
Drying (OPRP 2)	**Biological** Pathogenic Microorganisms	* Monitoring of EBN moisture content * Visual inspection on EBN during drying process	5	6	5	150	* Preventive program on HVAC system and equipment * Air quality monitoring * Perform humidity mapping on drying room	5	5	4	100
	Chemical Not significant		-	-	-	-		-	-	-	-
	Physical Presence of dust, cobwebs, pest droppings and metal fragments		3	5	5	75		3	4	5	60
Water Spraying (OPRP 3)	**Biological** Pathogenic Microorganisms	* Monitoring of water filtration system * QC check on the amount of water sprayed on the EBN	3	5	6	90	* Collection of water for microbiological and chemical testing	3	4	6	72
	Chemical Not significant		-	-	-	-		-	-	-	-
	Physical Not significant		-	-	-	-		-	-	-	-

Table 16: FMEA analysis and corrective actions implementation on CCPs

Processing Step	Risk	Surveillance Activity	S	O	D	RPN	Corrective Action	S'	O'	D'	RPN'
Heat Treatment **(CCP 1)**	**Biological** Pathogenic Microorganisms	Temperature monitoring probe Control of heat treatment parameters	7	6	6	252	* Regular maintenance and validation on steam tunnel *Temperature control (Monitoring of CL) Reject or repeat the process				
	Chemical Chemical contamination		7	5	5	175		7	4	3	84
	Physical Rarely found		-	-	-	-		-	-	-	-
Moisture Check **(CCP 2)**	**Biological** Outgrowth of mold	Moisture content monitoring probe, Control of cooling duration	8	6	5	240	* Reject any EBN that exceeded the critical limit of moisture content * Routine room temperature and humidity check	7	3	4	84
	Chemical Rarely found		-	-	-	-		-	-	-	-
	Physical Rarely found		-	-	-	-		-	-	-	-

3.5.3. *Ishikawa fish bone diagram*

Ishikawa diagram, a systematic technique that examine on the causes of identified problem and how the causes contributed to those effects. As the diagram structure is similar to a fish bone, it is known as fish bone diagram as well. Ishikawa diagram only applied to the CCPs in the raw unclean EBN processing. Well-established cleaning and sanitation program may minimize the occurrence of pathogens. Such combination of CCPs and FMEA are effective in food safety and quality assurance. Both can act as the verification tool to validate the results obtained. Rather than speculating which techniques are more effective, both methods have its gains and losses.

Possible causes in heat treatment stage were identified. Operational handling of steam tunnel was critical, excessive heat treatment duration and unreliable temperature control lead to product deterioration. Precursor step is essential to ensure the condition of EBN. Current study emphasis on the methods, machine and man factors. Inadequate time and temperature control, non-uniform heat distribution, equipment failures and lack of training were the possible causes for a problematic heat treatment process. Trained personnel should be endorsed where the personnel have the capability to diagnose faulty condition. Non-appropriate SOP probably magnified the likelihood of biological hazards occurrence. Major training challenges faced are time and location, subscribing online courses fulfilled the training needs and the schedule was more flexible than physical classes.

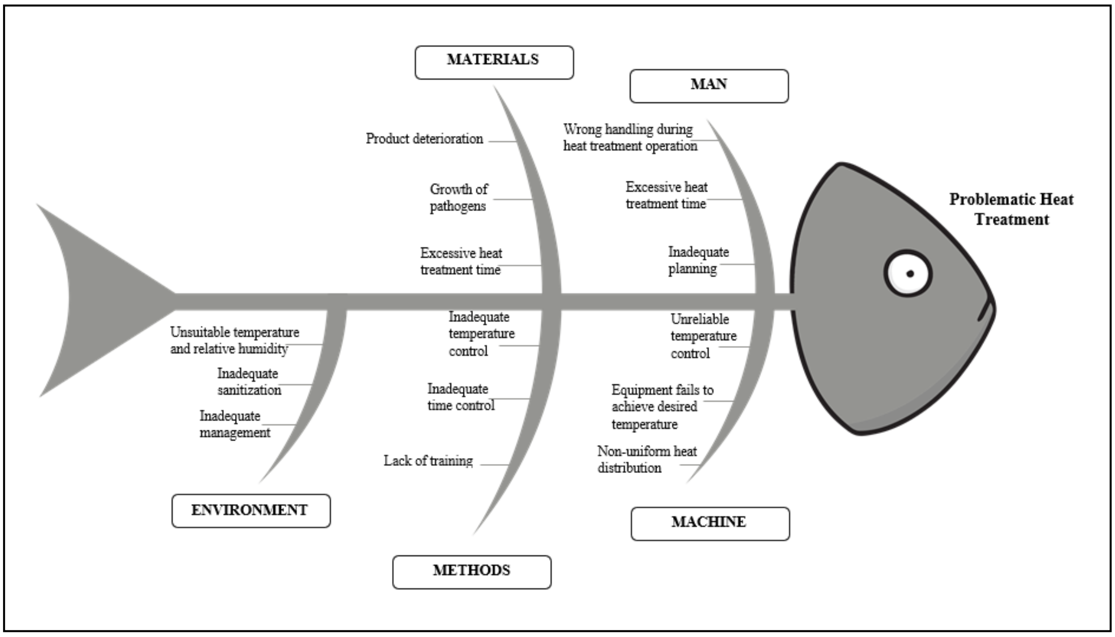

Figure 4: Ishikawa diagram for CCP 1 (heat treatment)

For CCP 2, possible causes were identified accordingly as well. Major hazards reside in the outgrowth of mold when the moisture content surpassed the critical limits. Moisture check stage is relied on the previous processing stage. Environment and method factors were considered in this case. Relative temperature and humidity of the IPQC room shall be continuously monitored and maintained to ensure the cooling efficiency of EBN were not afflicted. Moreover, issues arise from incompetency of personnel training with instantaneous consequences on product non-compliance. Substandard equipment functions due to negligence in maintenance became a concern as the accuracy and the precision of monitoring devices unable to generate valid results. Monitoring devices serve as the verification tools for key parameters in the process. To avoid future issue regarding the employee competency, online quality monitoring system is recommended to replace current off-line QC system.

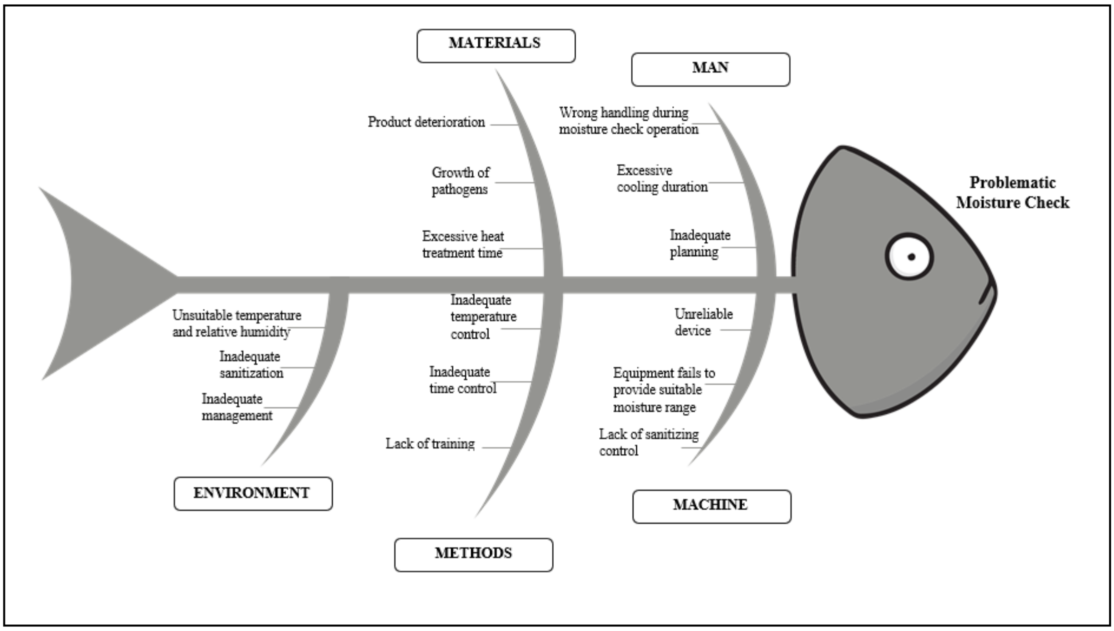

Figure 5: Ishikawa diagram for CCP 2 (moisture check)

Root cause analysis is not limited to Ishikawa diagram and FMEA, other approaches such as barrier analysis, fault-tree analysis, affinity diagram and et cetera are equally effective. Each tools utilize different methodologies and principles in terms of data requirements, collection, analysis and implementation, certain methods may require technical expertise to perform. Ease of use and simplicity are among the criteria of tool selection, even personnel with basic understandings of the tools capable of conducting without hassle.

3.6. *HACCP implementation challenges and misconceptions*

Undoubtedly changes are necessary for the conversion to HACCP system. Endurance is taken into the account, not all organizations able to apply HACCP system successfully. Respective root causes for food safety incidents are characterized to those shortcomings. Food safety management system should involve commitments from top management till the production floor employees. Table 17 addressed the core challenges during HACCP application:

Table 17: Main challenges during HACCP implementation (Kingphadung & Choothian 2017)

Issues	Descriptions
Top management commitment	• Solid fundamental is vital for HACCP implementation as it involves allocation of resources, manpower and financial investments. • Assistance in creating food safety policy and objectives along with HACCP team (Kingphadung & Choothian 2017). • Full cooperation with HACCP team eases the implementation of HACCP system.
Employee Engagement	• Employees should keen to the latest standards and procedures to meet the HACCP requirements. • Technical personnel should be updated regularly and competent to perform hazard analysis and food safety control. • All-level participation is needed to ease the workload of HACCP maintenance. • Consistent motivation is required to boost the employee morale.
Knowledge and relevant competencies	• HACCP team shall equip with strong knowledge and technique during hazard assessment and development of control measures (Maldonado-Siman et al. 2014). • For risk assessment and control plan buildup, statistical knowledge is needed to better assess the HACCP system (Dahiya et al. 2009).
Supplier control	• Entire HACCP system is connected to the product, from raw materials to the finished products. Suppliers are expected to equip with basic food safety knowledge. Lack of understanding on the food safety standards is correlated to the inefficient supplier control.
Facilities and equipment	• Facilities should be maintained and controlled under HACCP requirements. • Inappropriate premise structures during the early stage of establishment might need to adjust for compliance purpose. Factory area size and structures often become the limitations (Noor Hasnan et al. 2014). • CCP monitoring utilize equipment and frequent training should be provided to the personnel in charge of the operation.

HACCP shall not be viewed as the universal remedy for food safety related issues, its application does not prevent whole range of incidents. Certain major incidents could not be avoided even with the stringent deployment of HACCP system. Previously, persistent evaluation on the new hazards were not practiced which leads to irreversible havoc. Prevalent laxity toward food safety incidents is intolerable where the HACCP comes in place as a food safety management system. Most of the corporation set HACCP as a measure for authorities without proper understandings on the principles and values created. Vast amount of paperwork is generated where not much added value to the organization for the sake of satisfying the authorities. Objectives of HACCP are on the critical thinking and technical expertise rather than bunch of paperwork. Industry players often perceived HACCP as a stand-alone system and one-off exercise. If HACCP was considered as a sole system, then the interconnection between GMP, CCPs and verification activities are not existed and the overall effectiveness is depleted. Inadequate maintenance and review of the HACCP deviated its relevance to current practice (Motarjemi & Lelieveld 2014).

Lack of consideration on the human traffic and circulation of air and water within premise during flow diagram verification is frequently happened. Most of the HACCP implementer only focus on the product itself and oversee the employee movement. Due to the poor planning on product flow, cross-contamination is prone to occur (Motarjemi & Lelieveld 2014). Food processing facilities often differentiate the process steps as GMP and CCP. Adoption of hazard analysis enable us to determine which GMP having explicit relevancy to the food safety and the suitability of the control measures as PRP. Along with the application of HACCP, it further enhances the GMP by identifying GMP practices that require monitoring activities. Thus, we can conclude that both GMP and HACCP are correlated.

3.6.1. *Suggestions for further improvement*

Due to the high uncertainty in audit quality and reliability, each audit tools may result in different outcomes and complexity (Powell *et al.* 2013). Fusion of FMEA and HACCP displayed prominent accuracy and suitable for use during internal or external audits. Proper identification of weak components of HACCP system enables the facilities to figure out the bottleneck that require special attention. Audit criteria shall be reviewed in timely manner and design in a way that allow assessment of HACCP system performance (Trafialek & Kolanowski 2014). Deployment of FMEA as part of risk assessment enable us to evaluate the risk of each process in more comprehensive manner.

Even though the impact of the particular risk is unlikely to be minimized by the application of FMEA, it is worth to compare with hazard analysis adopted in MS 1480: 2019. OPRP has been defined in current studies which classified under Clause 8.5.2.4 – Selection and categorization of control measures in ISO 22000: 2018 Food Safety Management System. FSSC (Food Safety System Certification) 22000 is based on ISO 22000 system with additional sector-specific requirement and pre-requisite programs. FSSC 22000 is a complete certification scheme specifically for FSMS which provide the manufacturers an opportunity to focus on the food safety commitment in view of technical progress and improvements. Core benefit of FSSC 22000 is inclusion of FSMS validation of ISO 22000 that highly appreciated by global retail chains. Through the exposure of hazards on food via unexpected event may indicate dereliction of current system. Toropilova and Bystricky (2015) stated that most of the food business owners are satisfied with current status which do not intend to establish food safety control in more detailed due to the limitation of resources.

Consumer environments and production are highly volatile, lagging and insufficiency in HACCP development might affects its relevance. Due to the gradual behavioral changes toward HACCP application, hazard control is relegated by regular review pre-existing measures. Audit is one of the methods to reduce and resolve the discrepancies. Negligence of the fact of HACCP evolution caused control disorder and threaten its adequacy. Although the HACCP was established, overall efficiency of maintaining food safety control system is substandard and lead to failure in fulfilling customer requirements. Lack of competent personnel in handling FSMS serve as the pitfall for the establishment of HACCP.

4. Conclusion

HACCP system must be entrusted with mutual interaction and trust. Adoption of HACCP system shall follow the written procedure, there should be non-existence of gaps in terms of hazard control. Nonetheless, existence of gap is unavoidable and the motivation is the driven factor. Initial HACCP establishment is not complicated, how an organization continuously maintained and improved the HACCP remain a challenge, failure to evaluate the system may degrade into GMP system. Implementation of both GMP and HACCP system are manpower, technological and financial resources demanding and it is a comprehensive control system for manufacturing plant to deal with food-related hazards. Communication serves as the connection to the HACCP framework. Crucial understandings on HACCP concept with legal requirement fulfillment without the veto on creativity will penetrate the barriers of implementation. Proper risk analysis and communication methods in FSMS must be rectified and allocated in clear manner. Process approach was adopted during HACCP implementation in the raw unclean EBN processing. Two CCPs were identified which are heat treatment and moisture check of EBN. Critical limits denote the control of both CCPs and the deviation is properly monitored and controlled. Verification and recordkeeping were found out to be the portion that pose substantial food safety risks. Non-conformities appeared within the HACCP system especially on the employee with long service duration in the organization. Such integration of FMEA in verification phase of HACCP allow us to better assess the assurance system.

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