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MITIGATING OPERATION, QUALITY AND REGULATORY CHALLENGES IN THE PACKAGED DRINKING WATER INDUSTRY: A FAILURE MODE EFFECT ANALYSIS (FMEA) APPROACH

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ABSTRACT

Access to safe drinking water is vital for human development; however, challenges arising from industrialization, agriculture, and population growth threaten its availability. The packaged drinking water industry, a crucial alternative, encounters difficulties in meeting quality, operational, and regulatory requirements. Refillable polyethylene terephthalate (PET) jars, undergoing multiple cycles of refilling, pose higher risks of contamination, requiring more attention. This study advocates the use of a proactive method, Failure Mode and Effects Analysis (FMEA), to anticipate and prevent problems in the processing and refilling of PET water jars before they occur, promoting a proactive approach to quality and risk management.

Findings reveal inadequate cleaning of PET water jars with the highest Risk Priority Number (RPN) of 378, followed by aging of UV lamp, scaling on the UV lamp shield impacting the disinfection of product water and biological contamination due to unsanitary practices during manual filling of jars, each with RPNs of 315, 324, and 270. Addressing these top contributors promises substantial improvements in water quality. Implementing corrective actions reduced RPNs to 81, 54, 36, & 36, respectively.

This systematic application of FMEA yielded significant improvements in quality, safety, and reliability within the packaged drinking water industry. Proactive strategies developed through FMEA hold promise beyond the packaged drinking water industry, improving water quality management.

1. INTRODUCTION

Access to safe drinking water is universally acknowledged as a fundamental human right, as stated in Article 11(1) of the International Covenant on Economic, Social and Cultural Rights. However, the global challenges posed by rapid industrialization, extensive agricultural activities, and population growth threaten the availability of safe drinking water (Li et al., 2019; Li et al., 2022a, Li et al., 2022b, Sasakova et al., 2022). The UN World Water Development Report 2023, published by UNESCO, highlights that 26% of the world's population lacks safe drinking water, and 46% lacks access to well-managed sanitation facilities.

In response to these challenges, the packaged drinking water industry has emerged as a reliable alternative, meeting the demand for safe and high-quality drinking water. Recent development activities, rising living standards, and the adoption of new technologies drive

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the industry's growth. A report by Grey Views Research in January 2023 predicts that this industry will reach a market value of $36.21 billion by 2030, with a steady compound annual growth rate of 6-7%. Consumers, motivated by convenience, health concerns, and issues related to contamination, increasingly consider packaged drinking water as a substitute for tap water (Kajtazi et al., 2018; Freeco, 2020).

However, the packaged water industry faces challenges such as stringent regulations, quality issues, and operational efficiency of purification systems. These challenges pose threats to consumer health, business reputation, and sustainability, ranging from microbial contamination and chemical impurities to packaging defects, labeling inaccuracies, inefficient resource utilization, and adherence to industry standards (Bedada et al., 2018; Gad, 2018; Sharma, 2018; Singh, 2019).

To address these risks and maintain quality, safety, operational efficiency, and regulatory compliance, a proactive tool is necessary. Failure Mode and Effects Analysis (FMEA), widely used in the manufacturing industry, identifies potential failures and eliminates them to meet quality, operational, and regulatory requirements (Sharma & Srivastava 2018; Darmawan et al., 2020; Lee, 2021).

2. LITERATURE REVIEW

Recent studies have underscored the adaptability of Failure Mode and Effect Analysis (FMEA) across diverse sectors within the food manufacturing industry. These notable studies have delved into its effectiveness in various areas, including sardine production (Arif et al., 2022), sustainable food production practices (Soltanali et al., 2022), the food chain (Arslan et al., 2023), food safety management systems, and risk potency analysis for banana flakes machines (Aidil et al., 2023). Additionally, research has explored the application of FMEA in enhancing quality and efficiency in maize flake production (Bharsakade, et al., 2023). Moreover, there is a promising avenue for reducing food waste through a modified FMEA approach integrated with machine learning techniques. These studies collectively highlight the broad spectrum of FMEA's application, showcasing its role in addressing challenges and optimizing processes across different facets of the food manufacturing industry.

Despite these applications, a noticeable research gap exists in the utilization of FMEA within the packaged drinking water industry. Limited studies have explored this area, with Wu et al. (2018) being among the few to investigate the application of FMEA in this specific sector.

This study aims to bridge the existing gap by advocating for the systematic application of Failure Mode and Effects Analysis (FMEA) to identify and prioritize potential failure modes, assess their impacts, and develop proactive mitigation strategies, especially in the context of refilled PET (polyethylene terephthalate) water jars. As these jars undergo multiple cycles of refilling, they carry a higher risk of contamination. FMEA empowers data-driven decision-making, enhances product quality, ensures regulatory compliance, and builds and maintains consumer trust within the packaged drinking water industry.

The primary objective of this research is to strategically apply Failure Mode and Effects Analysis (FMEA) to address quality, operational, and regulatory challenges within the packaged drinking water industry. Specifically, this study aims to:

1. Identify potential failure modes, causes, and their effects within the packaged drinking water production and distribution processes.
2. Evaluate the severity (S), occurrence (O), and detectability (D) of these failure modes to prioritize critical areas for improvement.
3. Formulate and implement proactive strategies and controls to prevent or mitigate identified failure modes.
4. Assess the impact of FMEA on enhancing product quality, ensuring regulatory compliance, and building and maintaining consumer trust within the packaged drinking water industry.

This study will provide valuable insights into the systematic application of FMEA to address quality, operational and regulatory challenges, ultimately enhancing the quality, safety and reliability of packaged drinking water products.

3. METHODOLOGY

In this study, we chose a recently established packaged drinking water plant in Shamirpeth, India, as our research subject. Our objective is to apply the Failure Mode and Effects Analysis (FMEA) approach, commencing from the planning stage of the water purification process. The plant follows the fundamental purification process outlined in the Bureau of Indian Standard IS 14543 for packaged drinking water (IS 14543:2016). The purification process comprises multiple sequential stages (Figure 1).

Initially, water from a bore well is stored in a master tank to ensure a consistent supply during purification. It is then transferred to a smaller tank for efficient ozonation, optimizing ozone concentration, contact time, operational efficiency. This ensures more effective disinfection and contaminant removal in the water treatment process. Next, the water undergoes a multimedia filter (sand filter) to remove larger particles and debris. It progresses to the stage of activated carbon filtration (ACF), where activated carbon eliminates organic compounds, chlorine, odors, and tastes Gámiz et al. (2020). Following this, micron filtration preventing tiny particles, sediment, and contaminants from passing through and potentially interfering with the functioning of the RO membrane. In the subsequent filtration stage, water is pressured through a semi permeable Reverse Osmosis membrane (RO), selectively allowing water molecules to pass while rejecting contaminants, resulting in highly purified water. Anti scalant agents are introduced to prevent scale formation on RO membranes, enhancing overall purification efficiency (García-Triñanes, 2022, Mangal, 2022).

After the RO stage, the water enters the remineralization phase to achieve a balanced mineral composition and adjust pH to maintain the ideal range 6.5 to 8.5 (WHO) or 6-8.5 (IS14543) for optimal water quality. Subsequently, the water undergoes ultraviolet disinfection to eliminate harmful microorganisms and pathogens. The purified water is then stored in a stainless-steel tank for filling. Finally, ozonation is employed to further disinfect the purified water (Gray, 2014).

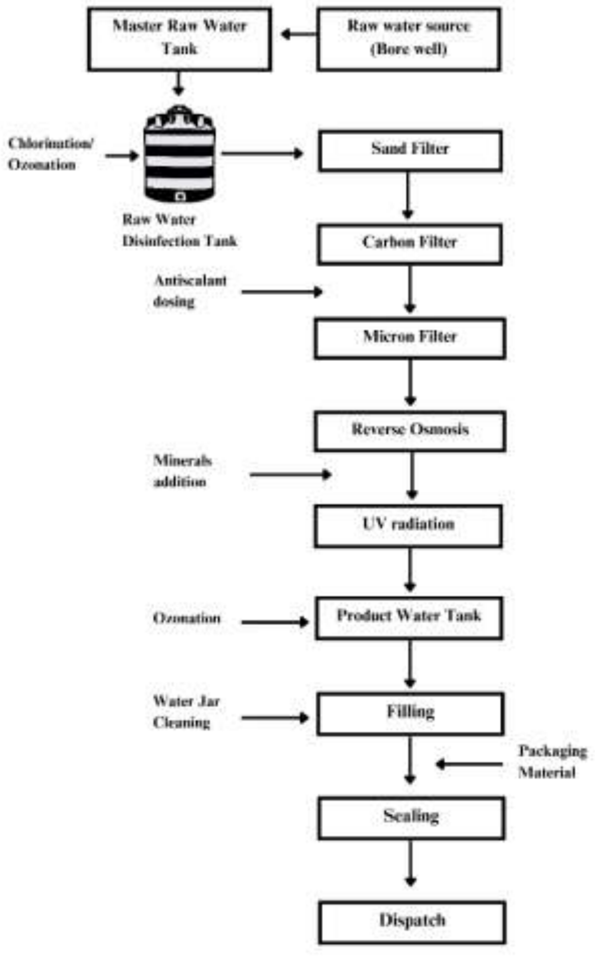
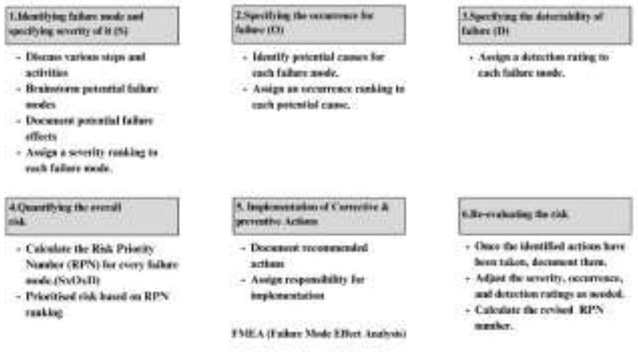


Figure 1. Packaged drinking water process flow chart

For each step in the filtration process shown in the flow diagram (Figure 1), we conducted a comprehensive failure mode and effects analysis (FMEA) consisting of six distinct stages (Figure 2).

We began by identifying potential failure modes through extensive discussions and brainstorming sessions. Subsequently, we assigned severity (S) rankings on a scale from 1 to 10, where a rating of 10 indicates the most significant impact in case of failure and 1 indicate least one. For each failure mode, we determined occurrence (O) ratings based on the probability of its occurrence, using a scale of 1 to 10, with higher rankings signifying a greater likelihood of occurrence. We also evaluated the detectability (D) of each failure before it reaches consumption, using a scale from 1 to 10, with 10 representing the lowest chance of detecting the failure before it occurs and 1 representing the greatest chance of detection. To calculate the Risk Priority Number (RPN), we used specialized software, FMEA Studio@2022, developed by IQA system LLC. Using the RPN rankings, we then prioritized a series of corrective and preventive actions. After the implementation of these actions, we recalculated the revised RPN values to ensure effective risk control and safety enhancement. This structured FMEA process not only uncovered potential issues but also helps in enabling proactive risk mitigation, ultimately enhancing the reliability on process and safety of the product. To facilitate analysis, each cause was assigned a Cause Number (CN), and we later analyzed each cause against the respective RPN. The theoretical range for Risk Priority Number (RPN) values spans from a minimum of 1 to a maximum of 1000, derived from the multiplication of severity, occurrence, and detectability factors (10 × 10 × 10). The establishment of a specific RPN threshold lacks standardization, leading organizations to adopt varied values based on the specific requirements of their processes or products. A notable approach in navigating this variability is the common utilization of an RPN value of 100, representing 10% of the maximum possible RPN.

$$[\boldsymbol{Risk\ Priority\ Number}(\boldsymbol{RPN}) = \boldsymbol{Sevirity}\ (\boldsymbol{S}) \times \boldsymbol{Occurence}(\boldsymbol{O}) \times \boldsymbol{Detection}(\boldsymbol{D})]$$


1.Identifying failure mode and specifying severity of it (S)
- Discuss various steps and activities
- Brainstorm potential failure modes
- Document potential failure effects
- Assign a severity ranking to each failure mode.

2.Specifying the occurrence for failure (O)
- Identify potential causes for each failure mode.
- Assign an occurrence ranking to each potential cause.

3.Specifying the detectability of failure (D)
- Assign a detection rating to each failure mode.

4.Quantifying the overall risk
- Calculate the Risk Priority Number (RPN) for every failure mode (SxOxD)
- Prioritised risk based on RPN ranking

5. Implementation of Corrective & preventive Actions
- Document recommended actions
- Assign responsibility for implementation

6.Re-evaluating the risk
- Once the identified actions have been taken, document them.
- Adjust the severity, occurrence, and detection ratings as needed.
- Calculate the revised RPN number.

FMEA (Failure Mode Effect Analysis)

Figure 2: FMEA (Failure Mode Effect Analysis) P:Process, S: Severity; O: Occurence; D: Detectability.

This choice reflects a practical strategy with a statistical confidence level of 90%. We discussed corrective and preventive actions for all causes, irrespective of rpn, but we focused and delved into detail when the assigned rpn was equal to or above 100.

4. RESULTS AND DISCUSSIONS

Table 1 presents a concise overview of an FMEA (Failure Mode Effect Analysis) conducted for the processing of Packaged Drinking Water. It displays the Risk Priority Number (RPN) assigned to each stage of water purification and the revised RPN after suggested corrective and preventive actions.

4.1 Raw water source:

Unplanned borehole drilling (CN02) can lead to microbial contamination due to potential leaks from nearby underground sewer lines. This poses a significant threat to the microbial quality of raw water sources. This contamination can endanger food safety and increase the costs of purification systems, as indicated by a Risk Priority Number (RPN) of 180. To effectively manage this risk, it is crucial to conduct regular inspections and immediately halt bore well operations upon detecting contamination. As a proactive measure, it is strongly advised to avoid installing bore wells in close proximity to public sewer lines, aligning with the guidance provided by the World Health Organization (WHO, 2003). Research has shown a direct link between the proximity of borewells to septic tanks and rising Biological Oxygen Demand (BOD) levels. The closer they are, the higher the BOD, underscoring the importance of carefully choosing the location of boreholes (Chove, 2017; Abanyie, 2023). Several studies recommend that boreholes should be drilled at a safe distance from septic tanks and pit latrines (Ugbebor et al., 2022; Samul, 2023). Before initiating any drilling project, it is crucial to gather comprehensive information about the underground utilities in the area. Begin by contacting local authorities and utility companies to obtain details about the location and depth of sewer lines. Hiring professional utility locating services is a valuable step, as they use specialized equipment to accurately identify the precise location of sewer lines. Additionally, acquiring and reviewing as-built drawings from the municipality or utility company can provide vital insights into the existing infrastructure. Physical site inspections should complement this data, as signs such as manhole covers, cleanouts, or sewer vents can further confirm the presence of sewer lines and aid in planning a safe drilling strategy. Simultaneously, implementing a systematic water quality monitoring system for early contamination detection can significantly reduce risks (RPN of 54).This proactive approach swiftly identifies and addresses contamination, thereby safeguarding public health and water quality.

Amidst the persistent rise in demand for packaged drinking water, the industry heavily relies on a stable and uncontaminated raw water source to cater to rising needs. So depletion of bore well water level (CN03) can be a challenge (RPN=240). It can be due to drilling for bore well without proper hydrological study. According to Heath's 1983 report in the US Geological Survey Water-Supply Paper 2220, conducting hydrological studies is imperative in decisions related to borehole drilling. This crucial study assesses groundwater availability, quality, and sustainability, guiding the selection of optimal drilling locations, borewell designs, and budget estimates. Furthermore, it ensures regulatory compliance and facilitates long-term water resource planning. Moreover, hydrological studies offer valuable insights into the dynamics of local aquifers, predict changes in water availability, and evaluate the environmental impact of groundwater extraction. This promotes environmentally responsible operations, as highlighted by Kulkarni (2021). These studies play a crucial role in enabling informed sourcing decisions, responsible water management, and the long-term supply of high-quality water. They not only uphold the integrity of the industry but also help preserve local water resources. Incorporating sustainable practices, such as optimizing extraction rates and employing water-efficient technologies, is crucial for preventing groundwater depletion and mitigating the risk of an unsustainable raw water source (RPN=80).These practices also observed in the findings of Bouhlel et al. (2023).

4.2 Raw water disinfection:

Chlorination (CN05) stands as a widely-used disinfection process for treating raw water; however, achieving the right balance in chlorine dosing is crucial. Insufficient doses raise the risk of microbial contamination, while excessive doses can lead to corrosion of reverse osmosis (RO) membranes, thereby reducing their efficiency and lifespan, as documented in studies by Gohil (2017) and Al-Abri (2019). Optimizing the chlorine dose is imperative, not only for operational efficiency but also for mitigating health risks.

It's worth noting that an excess of chlorine can lead to the production of harmful byproducts, such as trihalomethanes, haloacetic Acids as highlighted in reports by the World Health Organization (WHO) (2003, 2004, 2006) and Al-Abri (2019). The dual impact of chlorine on membranes and the formation of byproducts underscores the need to explore alternative disinfection methods while closely monitoring chlorine levels for effective water treatment.

Neglecting this aspect not only jeopardizes equipment durability but also increases the risk of regulatory non-compliance, with a high-Risk Priority Number (RPN) of 200, signifying a substantial risk. To mitigate these risks effectively, one should implement routine chlorine level monitoring, strengthen dechlorination systeme, provide personnel training, and utilize Internet of Things (IoT)-based sensors for real-time monitoring. This approach has been well-documented as successful in study by Zidan (2018), demonstrating how IoT-based sensors can help maintain optimal chlorine levels, thereby mitigating adverse effects and ensuring regulatory compliance while reducing the potential for human error.

Furthermore, it's prudent to consider exploring other disinfection methods, such as photocatalysts and nano-silver and ozonation (Ding et al., 2019, Lim, 2022). These alternative methods can serve as valuable tools in diversifying disinfection strategies and improving the overall water treatment process (RPN=32).

4.3 Activated Carbon filter:

Activated carbon filters (CN07) play a pivotal role in ensuring the safety and quality of packaged drinking water. However, their efficacy may decline over time due to the saturation of adsorption sites, influenced by the types and levels of impurities present in the source water, as noted in research by Zietzschmann (2016).

This saturation poses a threat to water quality, potentially compromising the filters' ability to remove contaminants. It is associated with a Risk Priority Number (RPN) of 175.

To effectively address this risk, it is crucial to implement corrective actions. These actions may include timely replacement or regeneration of the filter media and the adoption of daily backwash procedures to sustain filter efficiency. Additionally, frequent analysis of the iodine number is of paramount importance, as it serves as a measure of the adsorption capacity of activated carbon. These practices align with recommendations from the U.S. Environmental Protection Agency (USEPA) (1999) and are supported by the research findings of Devor (2013) on activated carbon filtration. Implementing these corrective and preventive measures can contribute to reducing the Risk Priority Number (RPN=42) associated with the saturation of adsorption sites and enhance the long-term effectiveness of activated carbon filters.

4.4 Micron filter

One critical failure mode is the clogging of the micron filter (CN08), attributed to high turbidity in the source water, insufficient backwashing or pre-filter maintenance, and variations in filter material quality. This issue can result in reduced flow rates, increased pressure drops, reduced RO efficiency, and potential microbial growth (RPN=210). The recommended corrective action is to promptly remove, inspect, clean, or replace the micron filter, adjusting cleaning and replacement frequencies. Effective measures include implementing a routine filter maintenance schedule, incorporating regular backwashing of prefilters and cleaning to prevent clogging of microne filter. Additionally, it's crucial to monitor source water turbidity, provide maintenance training to operators, and maintain spare filters. Always verify micron material specifications and source from reliable suppliers to ensure quality and consistency. By focusing on preventive actions organizations can reduce the occurrence of filter clogging and its undesirable effects (RPN=28).

4.5 Reverse osmosis:

In the packaged drinking water industry, reverse osmosis (RO) systems often face common challenges such as fouling and scaling (CN09).Fouling entails the accumulation of contaminants like suspended particles, organic matter, bacteria, and algae (Garcia 2022; Hoek et al., 2022) on the surface of the RO membrane. This accumulation leads to a decrease in water flow and overall system efficiency. Scaling, on the other hand, occurs when minerals precipitate on the membrane, obstructing water flow (Ruiz-García, 2017; Ahmed, 2023). Scaling and fouling leads to high operation & maintanace cost , low fux rate, membrane damage, high energy consumption (RPN=240).

The prevention of fouling and scaling in packaged drinking water RO systems relies significantly on effective pre-treatment phases. These phases not only enhance water quality and flow rates but also extend the lifespan of RO membranes, ultimately reducing operational costs (Ncube, 2021, Alsawaftah et al., 2021). Effective pre-treatment methods include sediment filtration, carbon filtration, and micro/ultrafiltration. Additionally, it is crucial to introduce anti-scalant chemicals, maintain appropriate system design and parameters, monitor and control system performance, schedule regular CIP (cleaning in place) and maintenance, consider water softening in areas with hard water, and conduct routine water quality analyses. These measures ensure the reliability and longevity of RO systems (RPN=32) in producing high-quality drinking water (Ahmed 2023).

4.6 UV light disinfection:

UV (ultraviolet) disinfection (CN10 & 11) is a critical step in the processing of packaged drinking water. However, a significant risk arises from potential insufficient UV intensity or lamp failure after prolonged use without proper maintenance, which can impact the microbial safety of water (RPN=324).UV lamps generally last between 8,760 to 14,000 hours, influenced by factors like operating temperature and frequency of use (USEPA, 1999). Lifespan may decrease due to on/off cycling and voltage instability. Furthermore, inadequate cleaning and chemical fouling of quartz tubes, identified by USEPA in 2006, can impair UV efficiency (RPN=315).The US EPA recommends using citric acid, sodium hydrosulphite, or any other mild acid for cleaning UV sleeve. Proper operation and maintenance (O&M) procedures are essential. Installing an operation hours tracking system for UV light is crucial. Additionally, the installation of a UV fail-safe sensor with alarms, as recommended by NSF/ANSI standards for microbial safety, can monitor and maintain UV systems effectively. Implementing these measures ensures the continued effectiveness of UV disinfection, thereby enhancing water safety and quality (RPN=36).

4.7 Cleaning of reused empty water Jars:

Investigating potential failure modes in the 20L empty can cleaning process has revealed that the degree of contamination can be influenced by various factors, including jar material, refill frequency, beverage type, and cleaning practices (Sun, 2017). This analysis has uncovered critical issues, notably insufficient cleaning due to untrained staff and poor hygiene (RPN=378). To address the issue of insufficient cleaning of water jars resulting from untrained staff (CN16) and poor hygiene practices, immediate corrective actions are essential. A comprehensive training program should be implemented to educate staff on proper cleaning procedures and emphasize the significance of maintaining high hygiene standards. Assigning dedicated supervisors to monitor and enforce compliance, establishing a feedback mechanism for staff, and revising and clarifying cleaning protocols are crucial steps. Additionally, awareness campaigns and the provision of personal protective equipment can further enhance staff understanding and adherence. For long-term prevention, periodic training refreshers, clear communication and enforcement of hygiene policies, provision of quality cleaning equipment with regular maintenance, and the implementation of incentives to motivate staff are necessary. Regular audits and inspections, accompanied by collaboration with health and safety authorities to stay informed about regulations, contribute to the establishment of a proactive and sustainable approach to maintaining water jar cleanliness and hygiene in the future (RPN=81).

Mechanical failure (CN17) of the cleaning machine, attributed to a lack of preventive maintenance and subpar equipment quality, jeopardized cleaning efficiency (RPN=200). Mitigating this risk involved the analysis of historical data on the cleaning machine, upgrading or repairing cleaning machinery, considering the implementation of redundancy measures for critical components to minimize downtime in case of future failures, and ensuring that spare parts are readily available to facilitate quick replacements when needed. Additionally, training for skill enhancement of operating staff was implemented. This measure can reduce the risk of frequent failure and enhance cleaning efficiency (RPN=72).

Inadequate rinsing (CN18), especially when linked to inefficient processes, faulty sensors, or low pressure in the rinsing valve resulting in valve choking, hinders the effective removal of contamination with a Risk Priority Number (RPN) of 144. Mitigating this risk requires essential actions, including process improvement, maintenance and cleaning schedules, verification, and regular sensor validation. Establishing a reject jar policy for non-compliant jars, designing jars for easier cleaning, and documenting washer operation and maintenance procedures (Food and Agriculture Organization, CXC 1-1969 n.d.; European Federation of Bottled Waters, 2012; Sun, 2017) are crucial measures that can reduce the contamination risk to an acceptable level (RPN=54).

4.8 Manual feeling of water jars:

While technology has undoubtedly brought automation into various sectors of the food industry, enhancing precision and reducing the risk of contamination from human handling, it's important to recognize that this progress comes at a cost. For small-scale businesses, these advancements may not always be within their budget, leaving many packaged drinking units in developing countries to rely on manual filling methods.

Manual filling techniques (CN20) necessitate human involvement, inherently carrying the risk of introducing biological, chemical, and physical contaminants (RPN=270). Moreover, manual filling often leads to limited production capacities, and losses due to spillage adversely affect both food safety and operational efficiency. To address these challenges, businesses must implement stringent measures, including promoting regular handwashing and the use of personal protective equipment (PPE). Providing ongoing hygiene and safety training for personnel, along with conducting medical examinations by health authorities, is equally crucial to minimize contamination risks (RPN=36).

Interestingly, a few studies have successfully demonstrated low-cost automated filling machines targeting small-scale industries (Mashilkar et al., 2015, Kalubarme et al., 2018; Nainani et al., 2020). These innovations can be instrumental in reducing wastage and increasing quality, safety, and production efficiency for small-scale operations.

4.9 Pacakged material

One potential source of concern in food packaging integrity is microbial contamination and pest infestation (CN23) from packaging materials (RPN=225). As highlighted by Lykov and Loboda (2022), microbial adhesion to packaging materials significantly affects the safety and shelf life of food products. Microorganisms can adhere to various materials, including stainless steel, polystyrene, polyethylene terephthalate, rubber, glass, and wood, forming resilient biofilms, as discussed in the study by Simoes et al. (2010). The formation of biofilms poses challenges for effective disinfection, as demonstrated in research by Rand et al. (2007).To address this issue, it is crucial to use chlorine water or a gentle disinfecting solution for sterilizing packaging materials. It is essential to ensure that residual concentrations meet standards to minimize the potential for harmful disinfection byproducts. Additionally, implementing SOPs for the proper handling of packaging materials, incorporating stringent practices on personnel hygiene (CN24), implementing Personal Protective Equipment (PPE) protocols, frequent pest control for storage area to reduce pest infestation, and providing comprehensive staff training for inspection and handling are imperative steps to reduce the risk of biological contamination and preserve product quality (RPN=36).

In the context of the packaged drinking water industry, which frequently employs polyethylene terephthalate (PET) plastic, a significant concern revolves around chemical migration (CN25) (Arvanitoyannis et al., 2004), such as phthalate esters (PAEs), Bisphenol A (BPA), heavy metals and others (RPN=225). These chemicals are known for their potential health effects (Bach, 2012; Li, 2019). Research study conducted by Xu (2019), highlights that chemical migration can occur under typical storage conditions, particularly when exposed to elevated temperatures in the summer (Allafi, 2020), extensive reuse (Gerassimidou, 2022), prolonged storage durations, and UV radiation.

To effectively address this issue and ensure consumer safety, proactive measures are essential. These include the use of certified polyethylene terephthalate (PET) bottles, optimization of storage conditions, regular migration tests to monitor compliance with migration limits, control of UV exposure, and the clear provision of storage guidelines on product labels. Implementing these integrated measures in the packaged drinking water industry can effectively prevent chemical migration, ensuring the safety and well-being of consumers (RPN=36).

Table 1: FMEA table for pacakaged drinking water processing

Water processing stages	Possible failure mode	Potential cause of failure	Cause No.	Possible Potential effect of failure	S	O	D	Initial RPN	Suggested Corrective & preventive action	S	O	D	Revised RPN
Raw water source borewell	**Contamination due to seepage of pollutants.**	Unsatisfactory sealing of the borewell, Poorly constructed borewell casing.	CN01	Ground Water quality degradation. Consumer health risk. Increae operation cost.	9	3	3	81	**CA:** Construct proper sanitary seal, Install a real-time monitoring system for water quality. **PA:** Always consult experienced drilling professionals and regularly monitor water quality.	-	-	-	-
		Unsafe distance between the borewell and the sewage line	CN02	Safety hazard. Regulatory Non-Compliance:	9	4	5	180	**CA:** immidiate inspection and shift to another water source. If contamination is found, disinfect the borewell. **PA:**Drill the borewell at a safe distance from sewer lines based on an analysis of local municipality data.	9	2	3	54
	Depletion of raw water source	Selecting a drilling point without conducting a proper hydrological study	CN03	cripple production processes	10	3	8	240	**CA:** Identify the cause. Consult hydrogeologist to evaluate situation. **PA:** Develop water resource management plan. Keep alternate source in case of emergency. Conducting a hydrogeological study before drilling a borewell. Monitor pump efficiency and if water salinity increase.	10	2	4	80
Raw Water Storage tank.	**Biological contamination**	Poorly maintained storage tanks and pipelines.	CN04	Consumer health risk. Increase operational cost. Fouling of RO membrane.	7	3	3	63	**CA:** Clean, and remove biofilm from the tank, clean dead ends of pipeline as well.Disinfect using appropriate methods. **PA:** Establish routine maintenance for cleaning and disinfection. Regulary test water quality.	-	-	-	-
	Chemical contamination.	Excessive use of chlorine/ Malfunctioning dosing pump	CN05	Damage to purification system, harmful byproduct. Regulatory non compliance	8	5	5	200	**CA:** Check chlorine level, re-calibrate dosing equipment, dilute, and retrain staff. **PA:** Establish SOPs, accurate calculations, install real-time monitoring IoT based sensor, continuous staff training. Install strong dechlorination systeme. Use non chemical disinfection method.	8	2	2	32
Sand filtration	**Clogging of sand media**	Prolonged use without proper maintenance.	CN06	Reduced filtration efficiency, increased pressure drops across the	6	3	4	72	**CA:** Implement a regular backwashing schedule to remove accumulated debris and sediment from the sand media.	-	-	-	-

				filter, and potential damage to the filter housing.					**PA**: Perform routine inspections and maintenance of the filter to ensure proper function.				
Activated carbon filtration	Reduced filtration efficiency	Carbon media saturation	CN07	Decreased water quality, Customer complaints. Increased levels of contaminants in the product water.	7	5	5	175	**CA:** Replace exhausted carbon media. **PA:** Establish a regular replacement schedule based on water usage and contaminant levels, and monitor the carbon filter's performance over time.	7	2	3	42
Micron filter	Clogging of Micron Filter	High turbidity in the source water. Insufficient maintenance of the pre filter. Quality variation in the filter material.	CN08	Reduced flow rate through the filter. Increased pressure drops across the filter. Impact on filtration efficiency and Microbial growth.	7	5	6	210	**CA:** Shut down, inspect, and clean or replace the clogged filter. Adjust Cleaning frequency. Verify filter material quality. **PA:** Establish a filter maintenance schedule, incorporating routine backwashing and cleaning. Monitor pressure differentials, flow rates, and water quality pre and post-micron filter regularly. Train operators and keep spare filters.	7	2	2	28
Reverse osmosis	Scaling & fouling, of membrane	No CIP (cleaning in place) in place	CN09	High operation cost, low flux rate, membrane damage, increase chemical usage, reduce water quality, high energy consumption.	8	6	5	240	**CA:** Employ suitable CIP methods Optimize pretreatment by adjusting pH and considering water softeners. **PA:** Continuously monitor feed water quality. Promptly follow CIP schedule. Provide operator training to detect scaling signs.	8	2	2	32
Ultraviolet (UV)	Insufficient UV Intensity, UV Lamp Burnout,	Aging of UV lamps	CN10	Inadequate disinfection, potentially leading to unsafe water quality. Risk to microbial safety. Regulatory non-compliance	9	6	6	324	**CA:** Replace the aged UV light and validate disinfection effectiveness. Install backup power to prevent power disruption. **PA:** Train staff on proper lamp replacement procedures. Install UV fail sensors with alarms for online monitoring. Track the life hours of the UV light.	9	2	2	36
		Scaling on the UV lamp shield	CN11	-do-	9	7	5	315	**CA:** Use alcohol or ammonia mixed with water and a lint-free cloth for UV cleaning to avoid leaving any residue. **PA:** Implement a regular cleaning and maintenance schedule.	9	2	3	54
Minerals dosing	Inaccurate minerals dosing	Equipment malfunction or calibration error.	CN12	Poor product quality, wastage of minerals. Regulatory non-compliance	5	2	3	30	**CA:** Implement regular equipment calibration or maintenance schedules. **PA**: Keep extra spare in case equipment malfunction.	-	-	-	-
		Variation in mineral concentrations in the source material.	CN13	-do-	5	2	3	30	**CA:** Use only certified food grade minerals Monitor the quality of source minerals to reduce variability. **PA:** Implement on	-	-	-	-

									inventory of mineral, always use certified food grade minerals.				
		Human error	CN14	-do-	5	6	2	60	**CA:** Only Train personnel should perform dosing activity. **PA:** Train personal and monitor the error in dosing	-	-	-	-
		Changes in water flow rate.	CN15	-do-	5	2	2	20	**CA:** Calibrate mineral dosing for current flow rate. **PA:** Install flow rate monitoring devise.	-	-	-	-
Empty PET jar Cleaning	Inefficient cleaning	Untrained staffs & poor hygiene.	CN16	Microbial & chemical contamination, endangering water quality and safety. Failure to meet regulatory standards.	9	7	6	378	**CA:** Implement a more rigorous cleaning procedure with defined parameters and regular validation. **PA:** Conduct regular audits and training sessions for cleaning personnel. Strick enforcement of hygiene protocol.	9	3	3	81
		Mechanical failure in cleaning machine.	CN17	Inefficient cleaning	8	5	5	200	**CA:** Implement a preventive maintenance schedule and have spare parts readily available. **PA:** Monitor equipment health in real-time and replace critical components before failure.	8	3	3	72
	Inadequate rinsing	faulty sensors, and unvalidated rinsing process.	CN18	Risk of chemical contamination	9	4	4	144	**CA:** Improve the rinsing process and implement verify system to validate inner rinsing process. **PA:** Regularly validate and recalibrate rinse sensors, and clean the rinsing valve as needed.	9	2	3	54
Automated Filling	Underfilled or Overfilled jars.	Inaccuratecalibration. Equipment wears and tear.	CN19	Not meeting metrological requirement, Wastage of resources.	7	3	3	63	**CA:** Calibrate filling equipment regularly.Employ automated systems for fill level monitoring and control. Establish a process to segregate and reprocess underfilled or overfilled water jars. **PA:** Perform routine equipment maintenance.Train operators in calibration procedures.	-	-	-	-
Manual Filling	Biological, Chemical and physical contamination.	Poor personal hygiene.	CN20	Risk to product Quality & safety. Regulatory non-Compliance	9	6	5	270	**CA:**Strict implementation of handwash practice & use of PPEs in filling section. **PA:** Conduct regular training on hygiene and Safety. Monitoring through hygiene test.	9	2	2	36
Sealing	Sealing Defects	Operational challenge of sealing equipment or human error.	CN21	Risk of product contamination. Potential health hazards. Product recalls and reputational damage. Regulatory non-compliance	9	3	3	81	**CA:** Regularly maintain and inspect sealing equipment. Introduce quality control checks, including visual seal inspection. **PA:** Establish a preventive maintenance schedule for sealing equipment. Train operators in sealing processes.	-	-	-	-

		Sub-standard packaging material.	CN22	Water leakage, contamination, and compromised product quality. Cost implication, customer Complaints	9	3	3	81	**CA:** Do immediate quality checks during packaging to detect sealing defects. Halt production and quarantine affected batches if sealing defects are found. **PA:** Establish quality control for packaging materials. Train operators to detect sealing issues. Periodically review and update material specifications.	-	-	-	-
Packaging Material	Biological contamination	Insects / Microorganisms from the unclean packaging material	CN23	Food safety and regulatory non-compliance	9	5	5	225	**CA:** Immediate inspection on hygiene condition, strict enforcement on use of PPEs. Disinfect your packaging material with suitable method. Ex. Rinse it with chlorine or ozonised water. **PA:** Develop SOP for implementing and monitoring stringent hygiene practice. Conduct regular training on importance of hygiene at work place. Monitor storage conditions for hygiene and conduct regular pest control activities.	9	2	2	36
		Contamination due to unsanitary practice/poor personal hygiene.	CN24	-do-	9	8	3	216		9	2	2	36
	Chemical Contamination	Migration of chemicals from the non-food grade packaging Materials.	CN25	-do-	9	4	7	225	**CA:** Use food grade packaging materials only. **PA:** Use certified product. Conduct migration/leachign test regularly.	9	2	2	36
	Physical Contamination	Foreign materials from the packaging materials.	CN26	-do-	7	4	2	56	**CA:** Immediate quality checks during packaging to detect and remove foreign materials. **PA:** Develop stringent supplier quality control protocols to ensure packaging materials are free from contaminants. Strict enforcement on use of PPEs. Frequent inspections.	-	-	-	-
Product water storage tank	Material corrosion or degradation.	High chloride content or other corrosive element in water. Sub standard material. .	CN27	Smell/taste, Chemical & microbial contamination, rusting particle in water.	7	3	3	63	**CA:** Clean tank interior and employ water treatment to reduce chloride levels if needed. **PA:** Use certified product. Corrosion-resistant stainless steel varient. Follow cleaning schedule. Monitor chloride content in water	-	-	-	-
	Biological contamination.	Inadequate cleaning and sanitation practices, open entry.	CN28	Food Safety hazard.	9	3	2	54	**CA:** Purge and sanitize the tank, seal potential entry points for contaminants.Review and improve cleaning and sanitation procedures. **PA:** Maintain proper tank seals and ventilation controls.Enforce strict hygiene protocols during tank maintenance. Regularly test and monitor water quality.	-	-	-	-

Ozonation (raw/product water)	Ozonation Equipment Failure	Lack of routine maintenance and inspection. Wear and tear of equipment components over time.	CN29	Inadequate disinfection, potentially leading to the presence of harmful microorganisms in the product water.	9	3	2	54	**CA:** Immediate repairs or replacements. Root cause investigation. **PA:** Regular maintenance and equipment inspection. Have backup ozone equipment available. Equipment performance audits. Install voltage stabilizer.	-	-	-	-

5. CONCLUSIONS

In conclusion, this study presents a thorough Failure Mode Effect Analysis (FMEA) for the processing of Packaged Drinking Water, providing valuable insights into potential risks and corresponding preventive measures at each production stage.

The assessment of raw water sources underscores the importance of regular inspections, strategic borehole placement, and the implementation of a water quality monitoring system to promptly detect and address contamination. Maintenance of raw water storage tanks and proper chlorination is identified as vital for operational efficiency and health safety. Exploring alternative disinfection methods like photocatalysts and nano-silver demonstrates a forward-looking approach to enhancing water treatment.

Analysis of filtration stages, including activated carbon and micron filters, emphasizes the critical need for timely replacement, regeneration, and preventive maintenance to prevent compromising water quality. Reverse osmosis systems require effective pre-treatment methods, implementation of the CIP (cleaning in place) process, and continuous monitoring to ensure reliability and longevity.

UV light disinfection demands stringent operation and maintenance procedures, including fail-safe sensors, tracking UV light operational hours, and regular cleaning, to guarantee microbial safety.

Cleaning and maintenance of reused water jars require rigorous procedures, training, and validation to minimize contamination risks. Manual filling of water jars, especially in smaller-scale industries, underscores the need for stringent hygiene measures, ongoing training, and considering low-cost automated filling machines.

Packaging material concerns underscore the critical role of equipment maintenance, quality control checks, and operator training in ensuring compliance with regulatory standards and protecting against contamination risks. Microbial contamination from packaging materials highlights the importance of sterilization practices and personnel hygiene.

Chemical migration risks associated with polyethylene terephthalate (PET) plastic bottles stress the need for certified materials, optimized storage conditions, migration tests, and clear storage guidelines to ensure consumer safety, particularly in light of the potential health effects linked to chemicals like phthalate esters (PAEs) and Bisphenol A (BPA).

While some failure modes and their associated causes may carry lower Risk Priority Numbers (RPN), it remains crucial to consistently monitor them, as even minor oversights can potentially escalate into significant failures. In essence, a holistic and proactive approach, integrating technological advancements, industry best practices, and compliance with regulatory standards, is paramount for sustaining the packaged drinking water industry. Addressing potential failure modes at each stage ensures product safety and quality, operation efficiency, contributing to environmental responsibility and consumer trust.

Continuous improvement, commitment to quality and consumer safety, ongoing innovation, and the adoption of sustainable practices are crucial for overcoming challenges and preserving industry integrity in the long run.

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