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QUALITY ASSURANCE OF BOTTLED DRINKING WATER USING THE HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM APPROACH

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Abstract
This paper discusses on implementing the design of a quality assurance system using the Hazard Analysis Critical Control Point HACCP approach. The HACCP is often considered by people who are not familiar as a problematic, complicated system that has to be left to experts. This system focuses on preventive measures by controlling the hazards of the drinking water treatment process to prevent the occurrence of diseases due to poisoned water and maintain product quality. This research was conducted at a bottled drinking water company. This company needs to commit to producing products that are hygienic and safe for consumption. In this study, laboratory testing of the finished goods was intended to determine the conformance quality of the product. The sample test result found the coliform bacteria in the bottled drinking water product. At last, this study developed critical control points in the daily operations by applying the whole HACCP principles based on the latest applicable standards.

Keywords:
Bottled Drinking Water;
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INTRODUCTION

Water is a human's essential need, but Municipal Waterworks has not been able to fulfil the high demand for drinking water. It leads to the rapid growth of drinking water in containers companies in Indonesia to make drinking water accessible for all. Drinking water in containers is massively consumed in our society. It is usually provided in fast-food restaurants, hotels, parties, seminars, and offices.

In producing drinking water, companies should surely be able to assure and maintain their quality to ensure consumers' satisfaction. Quality assurance refers to all planned and systematic actions that attempted to make sure that products produced in the factory fulfil all the requirements of quality standards. The quality assurance system can be implemented using the Hazard Analysis Critical Control Point (HACCP) system approach before the implementation of the ISO 22000 standard throughout the value chain [1]. The technique focuses on preventive measures to control the hazards during the processing process of bottled drinking water to prevent contaminated and poisoned water that may cause diseases.

HACCP is a systematic tool of quality assurance systems to identify, access, and control hazards, focusing on the prevention of identified hazards [2] [3]. The primary key to HACCP is the anticipation of hazards and identification of control points that prioritize the prevention measures and not relying too much on the product test on the final stage [2]. According to Mortimore and Wallace [3], people who are not familiar with HACCP often hold the misconception that it is an intricate, complicated system that has to be left to experts and can only be done by large companies.

Good Manufacturing Practice (GMP) and Sanitation Standard Operating Procedure (SSOP) are the basic requirements during the

implementation of HACCP. GMP is either an essential or a prerequisite program for the implementation of HACCP [4, 5, 6, 7, 8]. In Indonesia, GMP is implemented and regulated by Ministerial Regulation of the Ministry of Industry, No. 75/M-IND/PER/7/2010 on the guidelines in providing quality processed food [9]. SSOP are either written or objective instructions used by certain industries, specific for each food processing establishment, describing the procedures for performing daily operations in the production, storage, and transportation of the products [5]. It ensures the safety of the production system that includes scheduling the sanitation procedure, implementing monitoring programs, ensuring that all personnel understands sanitation, providing sanitation training, and promoting sanitation practices in the business unit [10] [11].

HACCP is a part of the quality management system that provides evidence which ensures that quality assurance requirement is well-fulfilled [12]. It is important to note that benefits and effectiveness in preventing identified hazards depend on two main issues, namely [13] prerequisite programs, and product and process design within the HACCP plan. Codex Alimentarius formulated the guidelines for implementing the HACCP system into twelve stages of systematic procedures contained in CAC/RCP 1-1969, Rev. 4-2003 [14]. The responsible government regulatory agencies are able to efficiently monitor and assess their proper implementation [15] [16].

In implementing the HACCP system, a company needs to consider all aspects, including national standards and specific regulations regarding drinking water products, such as SNI 3553:2015 [17], which says that chlorine residue should not exceed 0.1 mg/l. However, it is also important to note that a previous study by Morris [18] found that even low chlorine residue is still hazardous to human health. Hence, this paper describes the steps of designing the HACCP system at a bottled drinking water company. Referring to a study conducted by Praveena et al. [19] for conformity verification, this research employs laboratory testing to investigate whether product quality has already met all the requirements.

METHOD

This research was conducted in several steps. The first step is the direct observation on the production line, do some interviews, and discussion with the production department to give information on the existing problems. Then, the second step is data collecting, namely primary data and secondary data. Primary data includes a flowchart of the product potential hazards and the procedure of the production process. The secondary data includes GMP, SSOP documents, Indonesian national standards, general overview of the company, and other data related to the product. The third step is GMP was assessed using a questionnaire and verified directly in the field. Its formulation of the survey follows the standard requirement, namely the Ministerial Regulation of the Ministry of Industry, No. 75/M-IND/PER/7/2010. The fourth step is formulating SSOP questionnaire criteria based on its documentation standard [11]. The fifth step is samples were tested in a Laboratory of the Medical Faculty, Universitas Tarumanagara. This laboratory testing uses the Simple Random Sampling method to generate the time of taking the samples. The sixth step is the early stages of HACCP system planning, such as HACCP team formation, product description, identification of product usage, formulation of the flowchart, and verification of flowchart. Next, hazards are analyzed based on HACCP principles, which involves three stages, namely, hazard identification, significant hazard determination, and size control determination. Hazard identification is implemented by observing the production process of the drinking water and in-depth discussion with the company management. The possibility level and severity level of hazard are combined to determine its significant level, as shown in Table 1.

Determining the possibility of hazard based on the real situation of the field is categorized as follows; a) Low potential of a hazard: unlikely to happen, no historical record; b) Medium potential of a hazard: may happen, minimum historical records but have happened before; c) High potential of a hazard: often happen, based on existing historical records

Whereas determining the severity level of hazard based on its impact on human health is divided into; a) High level: life-threatening hazard; b) Moderate level: hazard may pose risks to human health; c) Low level: hazard causes the food or beverage becomes improper for consumption.

Table 1. The Significance Level of Hazard

		Severity		
		L	**M**	**H**
Reasonably likely to occur (possibility)	**L**	LL	ML	HL
	M	LM	MM	HM*
	H	LH.	MH*	HH*

*Generally thought as significant and will be considered in the process of determining the CCP
Information: L= Low, M= Medium, H= High

A significant hazard is analyzed to figure out whether it is regarded as the Critical Control Point (CCP), or not, using a decision support scheme, as can be seen in Figure 1. The hazards identified on CCP will be analyzed to figure out its critical limit to determine its tolerance level, whether it is safe enough for consumption or not. The next step is determining the monitoring procedure 4W+1H (*what*, *where*, *when*, *who*, *how*) and corrective actions for each CCP that deviates the agreed critical limit. The last stage will conclude the verification and documentation procedure that should be implemented.

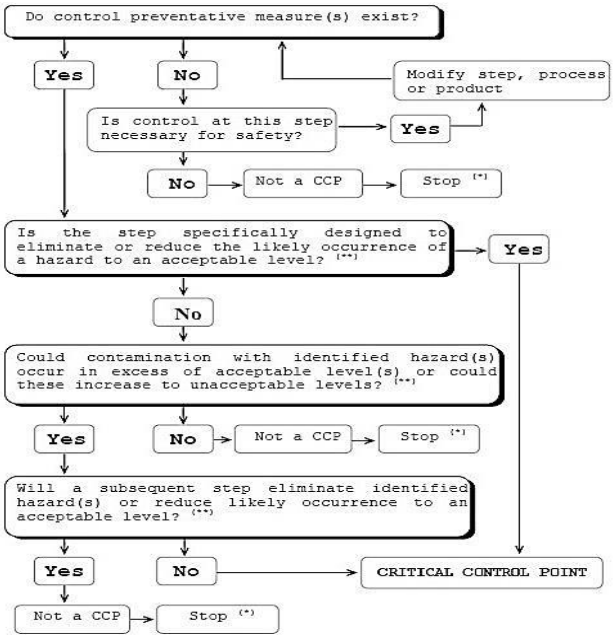

Figure 1. A Schematic of CCP Decision

RESULTS AND DISCUSSION

Based on the verification of the assessment results of GMP and SSOP, there are some findings in the field that should be fixed immediately by the company for supporting HACCP program implementation.

Laboratory Testing

Table 2 shows the determination process of the sampling time of finished goods.

Table 2. Random Sampling Time

Sample	Random Date	Random Time
1	26/03/2019	11.00
2	28/03/2019	14.00
3	29/03/2019	09.00

Laboratory test results show deviations from the latest regulation on the required quality of drinking water (SNI 3553:2015). Coliform bacteria are found, and thus, the drinking water is not safe enough to be consumed. Other than that, the company standard follows regulation SNI. 01-3553-2006 [20], but the Laboratory of the Medical Faculty supports Regulation of the Ministry of Health No. 492/MENKES/PER/IV/2010 [21].

Designing the HACCP System

Here are the stages of designing the HACCP system, among other things:

First stage: Forming a HACCP team

During this research, the HACCP team is formed, and it involves a factory manager, supervisor of quality control, and supervisor of production.

Second stage: Product description

Table 3 shows the product description containing complete information on the products.

Third stage: Identification of product usage

This drinking water product can be consumed directly by consumers without exceptions or going through the cooking process. It is sold in minimarkets, supermarkets, and offices. Everyone can consume this product.

Fourth stage: Formulating the flowchart

Flowchart of the production process is formulated to provide an overall overview of the production process manifested by the company to make it easier for people and other institutions to understand the process, as shown in Figure 2.

Table 3. Product Description

Parameter Description	Explanation
Product name	Bottled drinking water
Product composition	Water comes from water springs in Gunung Salak
Processing method	Water springs → container → sand filter → carbon filter → Filter I dan II →UV rays → finish tank → filling → packaging
Packaging	a. Gallon 19 litres b. Bottle (330 ml, 600 ml, dan 1500 ml) c. Cup 240 ml
Storage Condition	a. Clean and cool place b. Far from direct sunlight c. Far from a smelly object
Shelf Life	One year
Preparation and Serving Method	Direct consumption
Target Consumers	General
Distribution Method	Using closed pick-up vehicle and truck with a tarp cover
Labelling	Written information: Product name: bottled drinking water (it's brand) Netto: 240 ml, 600 ml, and 19 litres Production code
Product Selling Location	a. Supermarkets b. Minimarkets c. Offices

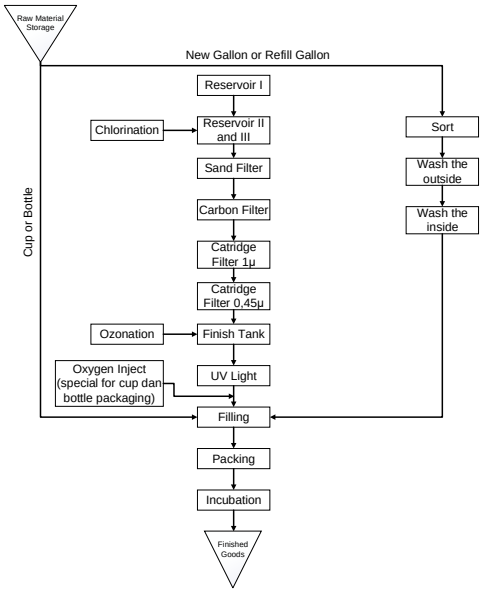

Figure 2. Flowchart of the Production Process of Bottled Drinking Water

Fifth stage: Verification of flowchart
A flowchart which had been plotted was checked and verified by the company management to provide a corrective recommendation.

Sixth stage: Hazard analysis
Hazards are classified into three criteria, namely biological, chemical, and physical factors, as shown in Table 4, Table 5, and Table 6, respectively. Table 7 shows the processes or items assessed as a significant hazard, which should be analyzed furthermore.

Table 4. Potential Biological Hazard [21]

Criteria	Types of Hazard	Maximum Level
Biological	*Coliform*	Negative
	Total Plate Count (TPC)	Total in the beginning: $1.0x10^2$ colony/ml Total in the end: $1.0x10^5$ colony/ml
	Algae	Negative
	Pseudomonas aeruginosa	Negative

Table 5. Potential Chemical Hazard [17][21]

Criteria	Types of Hazard	Maximum Level
Chemical	pH	6.0-8.5
	Organic substance (as $KmnO_4$)	1.0 mg/l
	Nitrite (as NO_2^-)	0.1 mg/l
	Nitrate (as NO_3^-)	44 mg/l
	Ammonium (NH_4^+)	0.15 mg/l
	Sulphate (SO_4^{2-})	200 mg/l
	Chloride (Cl^-)	250 mg/l
	Fluoride (F^-)	1.0 mg/l
	Cyanide (CN^-)	0.05 mg/l
	Iron (Fe)	0.1 mg/l
	Manganese (Mn)	0.05 mg/l
	Free Chlorine (Cl_2)	0.1 mg/l
	Chromium (Cr)	0.05 mg/l
	Barium (Ba)	0.7 mg/l
	Boron (B)	2.4 mg/l
	Selenium (Se)	0.01 mg/l
	Bromate	0.01 mg/l
	Silver (Ag)	0.025 mg/l
	Carbon dioxide level (CO_2)	3000-5890 mg/l
	Oxygen level (O_2) dissolved in the beginning **)	40.0 mg/l
	Oxygen level (O_2) dissolved in the end***)	20.0 mg/l
	Metal contamination: a. Lead (Pb) b. Copper (Cu) c. Cadmium (Cd)	 a. 0.005 mg/l b. 0.5 mg/l c. 0.003 mg/l
	Mercury (Hg)	0.001 mg/l
	Arsenic contamination (As)	0.01 mg/l

Note: **) at the factory, ***) in the market

Table 6. Potential Physical Hazard [21]

Criteria	Types of Hazard	Maximum Level
Physical	Odourless	Odourless
	Colour	5 Unit Pt-Co
	Total Dissolve Solid (TDS)	500 mg/l
	Turbidity	1.5 NTU
	Flavour	Normal

Seventh stage: Determination of critical control point (CCP) using a decision support scheme.
Table 8 shows how the steps in deciding a significant hazard as a critical control point.

Table 7. The Results of Significant Hazard [22]

No.	Process or item	Type of Hazard	Hazard	Source of Hazard	Is this hazard significant?			
					Possibility Level	Severity Level	Yes	No
1	Reception of new gallons	P	a. Dirt b. Smell	a. Plastic shreds, material leftovers b. Additive substance from the gallon	L	L		N
		B	TPC and Coliform	Process deviates from GMP.	L	M		N
		C	-	-	-	-	-	-
2	Reception of refill gallons	P	a. Dirt b. Oil c. Smell	a. Used gallon b. Trash/unidentified chemicals in the used gallon	M	M		N
		B	TPC and Coliform	Microbiology	M	M		N
		C	-	-	-	-	-	-
3	Reception of gallon caps	P	Dirt	Plastic shreds, material leftovers	L	L		N
		B	TPC, Coliform, and Algae	Microbiology	L	M		N
		C	-	-	-	-	-	-
4	Reception of gallon stickers	P	Imperfect stickers cut, faded prints	Installation on gallons is flawed	L	L		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
5	Reception of P.E.T. bottle	P	-	-	-	-	-	-
		B	TPC and Coliform	Microbiology	L	M		N
		C	-	-	-	-	-	-
6	Reception of bottle caps	P	-	-	-	-	-	-
		B	TPC and Coliform	Microbiology	L	M		N
		C	-	-	-	-	-	-
7	Reception of cups	P	-	-	-	-	-	-
		B	TPC and Coliform	Microbiology	L	M		N
		C	-	-	-	-	-	-
8	Reception of cups' lid	P	Unclear printing	Unstandardized printing	L	L		N
		B	TPC and Coliform	Microbiology	L	M		N
		C	-	-	-	-	-	-
9	raw water	P	Dirt, high turbidity	Dust, sand, rock, mud	L	L		N
		B	TPC, coliform, and algae	Microbiology	L	M		N
		C	pH and TDS are not standard	raw water is on low quality	L	H		N
10	Reservoir tank	P	High turbidity	Dust, sand, rock, mud	M	L		N
		B	TPC, coliform, and algae	Microbiology	M	M		N
		C	Chlorine	Chlorine addition exceeds standard	L	H		N
11	Sand filter	P	High turbidity	Dust, sand, rock, mud	L	L		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
12	Carbon Filter	P	Small carbon flakes	Filter condition	L	L		N
		B	-	-	-	-	-	-
		C	Chlorine	Absorption is no maximum	M	H	Y	
13	Filter 1 µm	P	Small dirt particles	Material flakes from cartridge filter	L	M		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
14	Filter 0.45 µm	P	Small dirt particles	Material flakes from cartridge filter	L	M		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
15	Finish tank	P	a. Strong smell b. Dust particles	a. Ozone concentration exceeds the standard b. Poorly closed tank	M	M		N
		B	TPC and Coliform	Ozone concentration is not standard	H	M	Y	
		C	-	-	-	-	-	-

Continuous of Table 7. The Results of Significant Hazard [22]

No.	Process or item	Type of Hazard	Hazard	Source of Hazard	Is this hazard significant?			
					Possibility Level	Severity Level	Yes	No
16	Oxygen tank	P	-	-	-	-	-	-
		B	-	-	-	-	-	-
		C	Oxygen level below the standard	Pressure in the process of oxygen mixing is decreasing	L	M		N
17	Filling	P	-	-	-	-	-	-
		B	TPC and Coliform	Workers and air	M	M		N
		C	-	-	-	-	-	-
18	Coding	P	Wrong expiry date	machine setting error	L	M		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
19	Labelling	P	Unfit moulding, messy wrinkles, improper position	Unstandardized printing (labelling and steamer machine)	L	L		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
20	Packing	P	Carton is not tightly closed	Carton dimension is not standard	L	L		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
21	Palleting	P	Dirty palette condition	Dirty and dusty area	M	L		N
		B	-	-	-	-	-	-
		C	-	-	-	-	-	-
22	Delivering	P	Dirty and dusty area	Carton dimension is not standard	M	L		N
		B, C	-	-	-	-	-	-

Information: P = physical hazard, B = biological hazard, C = chemical hazard

Table 8. The Results of CCP Decision

Process or item	P1	P1a	P2	P3	P4	Categorized as CCP?
	Yes: P2	Yes: Modification	Yes: CCP.	Yes: P4	Yes: Not CCP.	
	No: P1a	No: Not CCP.	No: P3	No: Not CCP.	No: CCP.	
Carbon Filter (chemical: Chlorine absorption is not optimal)	Yes		Yes			Yes
Finish Tank (concentration of ozone is below standard)	Yes		Yes			Yes

Eighth stage: Determination of critical limit

As mentioned earlier, a critical limit is designed based on SNI 3553:2015. The critical limit that has been decided is Chlorine residue at 0 mg/L, finish tank ozone at 0.4-0.6 mg/L, and content of ozone in the product at 0.1-0.4 mg/L.

Ninth and tenth stages: Determination of monitoring procedure and corrective actions

Corrective action is needed to find out what to be done after deviation occurred on the critical limit. The monitoring procedure that can be implemented is what (Chlorine residue), who (QC department), when (2 times a day, before and after breaks), how (using chlorine test kit). Corrective actions can be manifested if chlorine residue is found in the product so that production can be stopped, and active carbon is replaced with the new one.

Eleventh stage: Determination of verification procedure

The verification stage is implemented by investigating the finished goods to know the strong indicator of the implementation of the HACCP system.

Twelfth stage: Creating documentation

The documentation process starts from the prerequisite program to the implementation of the HACCP program itself and continuing onward. The prerequisite program documentation is related to the critical point, while the literature in implementing the HACCP program is closely related to the critical control point.

CONCLUSION

This research shows the deviation of biological criteria in the drinking water product because of the *coliform* bacteria found through a laboratory test. The standard guideline used in the company is SNI. 01-3553-2006, but the latest standard requirement of mineral water is on SNI. 3553:2015. Therefore, from this research finding, we suggest that the company utilizes the new guidelines, namely SNI. 3553:2015. This study developed critical control points which should be controlled by the company, such as carbon filter and finish tank, by implementing HACCP principles. Besides, quality control is also executed to anticipate all possible hazards that may happen in the form of a control point. The limitation of this study is their subjective judgments by management in determining the significance level of hazard.

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