Good manufacturing practices for risk management in food safety sustainability: An empirical study

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Abstract. Food is an essential need for the sustainability of human life so that consumers have the right to get a product that is safe for consumption. However, food poisoning cases due to the risk of biological, chemical, physical, and other contamination still occur frequently. In this study, an empirical investigation was conducted on apple pie production in a food processing SME that is known to have a risk of physical, chemical, and biological. This study used the hazard analysis and critical control point (HACCP) and good manufacturing practice (GMP) approaches to analyze each production process's hazards. This study also identified factors that harm using failure mode and effect analysis (FMEA) and provided recommendations for improving food safety and security for the SME business sustainability.

1. Introduction

Food is the most basic need for humans. Consumers have a right to get food that is safe for consumption [1, 2]. The food product that is appropriate to consume must meet several criteria: safe, healthy, excellent, and halal [3, 4]. Regarding government regulation, food safety, quality, and nutrition are defined as a condition to prevent foods from the biological, chemical, physical, and other hazards that could harm the consumers [5].

In 2016, the National Agency of Drug and Food Control (BPOM) Indonesia conducted a study about the safety and the quality of food products on the market. Their study found that 3,957 out of 26,537 products on the market were ineligible [6]. They also found 110 cases of food poisoning in Indonesia. One of the causes of food poisoning was food-processed consumption [7]. One of the foods processed industry was the SME in Indonesia [8, 9].

This study was conducted at the SME in Indonesia that produced apple pie. Apple products are one of the superior local products in this region [10]. The SME produced approximately 600 packs/day. Unfortunately, the SME has not yet implemented food safety standards. The implementation of food safety standards was essential to control the production process [11, 12]. The workers, raw materials, or the production process that not followed the standard operating procedure (SOP) causes the potential hazard [13]. The workers in the SME did not follow the SME's SOP. For example, the workers did not use the standard personal protective equipment (PPE) and hand gloves and masked when processing the apple pie. Figure 1 shows an example of potential hazards.
Based on a preliminary study, there were 11 processes to make the apple pie. It began with gathering the raw materials (apples and flour), sorting and cutting the fruit, washing, grating into small parts, cooking until the texture changed into a jam, making the pie skin (inner and outer skin), mixing the inner and outer skin, moulding, baking, cooling the apple pie and packing. In each production process may cause a potential hazard that can lead to food risks [14]. One example is in the grating process. If the grating machine and equipment that were not properly sterilized, it might cause the rusty engine to contaminate the apple. The other hazards were the pesticides that attached to apples and apple oxidation. Therefore, this study aims to identify hazards for minimizing the risks that can occur at any stage of the apple pie production process.

In this study, the apple pie's production process hazards were analyzed with hazard analysis and critical control point (HACCP) approach. HACCP is a monitoring system to prevent the hazard in food product [15-17]. HACCP approach may ensure the products are safe for human consumption by installing the proper tools to detect the occurrence of contamination and indicate a corrective action whenever the contamination occurs [18]. HACCP is used to analyze the biological, chemical, and physical hazards, in particular, apple pie's production process [19-22]. Biological hazard is the macro-biology and microbiology that contain in food. Chemical hazard is the various chemical elements that cause pollution or contaminants in food. A physical hazard is the foreign objects in physical form, which generally are not present in food that may cause disease.

In HACCP, it is essential to identify the critical control point (CCP). CCP is a step at which control could be applied. It is essential to prevent or eliminate food safety or reduces it to an acceptable level [23, 24]. The next phase after determines which process is CCP was to conduct a deviation analysis at each CCP process with failure mode and effect analysis (FMEA). The aim of using the FMEA method was to determine the hazard that could be minimized or eliminated [25]. The FMEA result would be the priority list to improve the implementation of good manufacturing practices (GMP) [26]. In addition to overcoming food hazards and risks in apple pie production, proposed improvements regarding GMP aspects are also expected to help business sustainability.

2. Research Method
The data was collected by observing the production process and identifying the potential hazards in each process. The next phase was a critical control point (CCP) identification. This phase can be controlled and very important to prevent the potential food safety hazard or minimize the hazard to an acceptable level. The CCP was conducted through the decision tree, as shown in Figure 2. The phase continued with critical limit determination. The critical limit is the minimum and maximum value of biological, chemical, or physical parameters that must be controlled at CCP [27, 28]. The critical limit separates acceptability from unacceptability in food processing.
Figure 2. CCP decision tree.

The next phase was identifying the implementation of good manufacturing practices (GMP) at the SME. GMP is a system that assures proper design, monitoring, and control of manufacturing processes and facilities [29]. GMP’s implementation avoids or reduces the contamination of food by biological, chemical, and physical hazards [30].

The study continued with measuring potential hazards at CCP with failure mode and effect analysis (FMEA). The FMEA method analyzes the severity, the occurrence, and the level of difficulty or ease of hazard control (detection) [31]. The FMEA result was a risk priority number (RPN) of each potential hazard obtained through the multiplication of the severity, occurrence, and detection rank [32, 33]. The RPN was used to determine critical RPN. The critical RPN was obtained based on equation (1) [34]. The potential hazard with the RPN score equal to or higher than the critical RPN must be the priority in recommendation planning [35].

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RPN = \frac{\text{Total RPN}}{\Sigma \text{risk}}
\]  

3. Results and Discussion
This phase included hazard identification, CCP analysis, critical limit determination, GMP analysis, identification of potential hazards at CCP with FMEA, and recommendation for this study.

3.1. Hazard identification
In this phase, the potential hazards were identified. There were three types of hazards, i.e., biological hazards, chemical hazards, and physical hazards. The hazards were identified at each production process, starting from collecting the raw materials until packing the apple pie. For example, for the baking process, the biological hazards were *Escherichia coli* and *Staphylococcus aureus*. The hazard identification is shown in Table 1.

3.2. Critical control point (CCP) analysis
Critical Control Point (CCP) was identified from the collecting raw materials process until the packing process. CCP analysis was identified using a decision tree, as shown in Figure 2. Based on the CCP analysis, seven processes were included as CCP. One of the examples is collecting the raw material process. There was a chemical hazard (a pesticide that was still left at the apple) and a physical hazard (soil, hair, dust). CCP analysis is shown in Table 2.
### 3.3. Critical limit identification

The critical limit is used to determine the control limit for each Critical Control Point (CCP). The critical limit for CCP could be defined as one or more tolerance levels that must be met to ensure that CCP has controlled the hazard effectively. Critical limit identification was referred to as the National Agency of Drug and Food Control (BPOM) standards. Critical limit identification is shown in Table 3.

**Table 1.** Hazard identification in apple pie production process.

| No | Process                        | Biological hazard       | Chemical Hazard          | Physical Hazard          |
|----|--------------------------------|-------------------------|--------------------------|--------------------------|
| 1  | Collecting the raw materials  | Patulin from fungus,    | Pesticide                | Soil, hair, dust         |
|    | a. Apple                       | *Escherichia coli*      |                          |                          |
|    | b. Flour, water, sugar, oil, salt | *Staphylococcus aureus* |                          |                          |
| 2  | Sorting and cutting the apple  | Patulin from fungus,    | Fe (iron) from the knife,| Fruit seed, soil, dust   |
|    |                               | *Escherichia coli*      | pesticide                |                          |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 3  | Cleaning                       | Patulin from fungus,    | Pesticide, apple oxidation| Fruit seed, soil         |
|    |                               | *Escherichia coli*      |                          |                          |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 4  | Grating                        | Patulin from fungus,    | Fe (iron) from the grating| Hair, dust               |
|    |                               | *Escherichia coli*      | machine, pesticide, and apple oxidation |                          |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 5  | Cooking the apple              | Patulin from fungus,    | Fe (iron) from the knife and| Hair, plastic, dust      |
|    |                               | *Escherichia coli*      | machine, pesticide, and apple oxidation |                          |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 6  | Making the pie skin           | *Escherichia coli*      | -                        | Hair, dust               |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 7  | Combining inner and outer skin | *Escherichia coli*      | Plastic residue          | Dust, hair, and other foreign things |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 8  | Molding                        | *Escherichia coli*      | -                        | Hair, dust               |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 9  | Baking                         | *Escherichia coli*      | -                        | -                        |
|    |                               | *Staphylococcus aureus* |                          |                          |
| 10 | Cooling                        | -                       | -                        | Dust                     |
| 11 | Packing                        | -                       | -                        | Dust                     |

**Table 2.** CCP analysis in apple pie production process.

| No  | Process                      | Q1  | Q2  | Q3  | Q4  | CCP? |
|-----|------------------------------|-----|-----|-----|-----|------|
| 1   | Collecting raw materials     | Yes | Yes | -   | -   | Yes  |
| 2   | Cleaning the apple           | Yes | Yes | -   | -   | Yes  |
| 3   | Grating                      | Yes | Yes | -   | -   | Yes  |
| 4   | Cooking the apple            | Yes | Yes | -   | -   | Yes  |
| 5   | Combining inner and outer skin| Yes | No  | Yes | No  | Yes  |
| 6   | Baking                       | Yes | Yes | -   | -   | Yes  |
| 7   | Cooling the pie              | Yes | No  | Yes | No  | Yes  |

### 3.4. Good manufacturing practices (GMP) analysis

Good Manufacturing Practices (GMP) is a guide for food-producing to meet food products [36]. According to the Ministry of Industry of Indonesia about GMP guidelines, there are 14 requirements for food producing, e.g., the factory location and environment, the factory facility, sanitation, employees, and process control.

Based on the analysis, GMP implementation at the SME had not good enough because several GMP aspects could be optimized. GMP is essential to support the HACCP method, so the apple pie product has a good quality and also safe to consume.
Table 3. Critical limit identification at apple pie production process.

| No  | Process                          | Potential Hazard                                                                 | Critical limit                                                                 |
|-----|----------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| 1.  | Collecting raw materials         | 1. Chemical: pesticide                                                          | 1. Control the use of pesticides. Following the maximum dose, the maximum residue for benomyl pesticide is BMR 5 mg/kg |
|     |                                  | 2. Physical: hair, plastic, soil, dust                                          | 2. There are no rotten fruits, freckles, or dusty                              |
| 2.  | Cleaning the apple               | Chemical: pesticide and apple oxidation                                        | The apple should be cleaned using the running water.                           |
| 3.  | Grating                          | Chemical: Fe (iron) rust                                                        | The machine and equipment should be inspected regularly.                       |
| 4.  | Cooking the apple                | Biological: Patulin from fungus, Escherichia coli, Staphylococcus aureus        | The cooking temperature must be 200°C.                                         |
| 5.  | Combining inner and outer skin   | Chemical: plastic residue                                                      | Keep the cleanliness of the plastic, replace the plastic regularly (not using plastic twice). |
| 6.  | Baking                           | Chemical: Escherichia coli, Staphylococcus aureus                               | The temperature should be 200°C for top heat and 150°C for bottom heat.       |
| 7.  | Cooling the pie                  | Physical: Dust                                                                  | The product must be protected from the dust.                                   |

3.5. Potential failure identification at critical control point (CCP)

This study used FMEA to identify the deviation at CCP. FMEA had three components to be assessed: severity (S), occurrence (O), and ease to detect (detection/D). In this study, each score was obtained through brainstorming with the SME. The output was a risk priority number (RPN) obtained through multiplying the score of each component.

There were eight potential failures at CCP. One of the potential failures is the pesticide that is still left at the apple. The potential cause of the failure was that the supplier did not clean the apple well, and the SME worker did not check the apple quality from the supplier. The potential effect of failure was that the apple could endanger the consumer. The complete analysis and assessment for each potential failure are shown in Table 4.

The next phase was the critical RPN determination using Eq. (1). The total RPN was 200, and the total risk was 8, so the critical RPN was 25. If the potential failure has RPN higher than 25, the potential failure should be prioritized for further analysis. According to Table 4, three potential failures have a score higher than 25. The three potential failures were the pesticide that was still left at the apple, the rusty machine, and the bacteria's growth possibility.

3.6. Monitoring system recommendation

Monitoring system recommendation is a suggestion for the SME to improve the system so that the SME could minimize/eliminate the hazard, especially at the CCP process. The recommendations were given based on the potential failures that have a score higher than 25. It was recommended for the SME to implement Standard Operating Procedure (SOP) for each process, especially for cleaning the apple and cleaning the machining process. The SOP would be a guideline that every worker should follow SOP for each process.

The other recommendation for the SME was making and implementing the rules about everything that the workers should pay attention to before do the production process. The rules must include the standard of personal protective equipment (PPE) and worker hygiene. The supervisor should read the rules every day and brief the worker before they start to work. In order to control the obedience of the rules, every worker should fill the check-sheet. The check-sheet contained the PPE list that needs to be used before the workers do the production process.

With monitoring system recommendation, it was expected to minimize or eliminate the hazard at each CCP so that the SME could produce the best quality of apple pie. These monitoring system recommendations should be conducted and monitored by managerial and all related elements to improve the SME.
Table 4. FMEA analysis in apple pie production process.

| No | Potential Failure | Failure Mode | Failure Effect | S  | O  | D  | RPN |
|----|-------------------|--------------|----------------|----|----|----|-----|
| 1. | The pesticide is still left at the apple | The supplier did not clean the apple well, and the SME worker did not check the apple quality from the supplier | Endanger consumer health | 2  | 4  | 4  | 32  |
| 2. | The apple seed left | The worker did not clean the apple seed well after cutting the apple | Endanger consumer health | 1  | 6  | 4  | 24  |
| 3. | Contamination from the plastic, soil, and dust at the apple | The supplier did not clean the apple well | The bacteria grow in the human body | 4  | 3  | 1  | 12  |
| 4. | Apple browning | The cut or grate apple left open | The benefit from the apple is a decrease | 1  | 6  | 4  | 24  |
| 5. | The apple cleaned by the water in the tub | The worker did not clean the apple well | The water in the tub could contaminate the apple | 3  | 2  | 1  | 6   |
| 6. | The rusty machine | The machine did not clean properly | Endanger consumer health | 8  | 6  | 1  | 48  |
| 7. | The growth possibility of bacteria | The worker did not follow the SOP. For example: did not use the hand gloves | Endanger consumer health | 7  | 6  | 1  | 42  |
| 8. | Repeated use of plastic | The plastic was not cleaned before the second use | Endanger consumer health | 3  | 4  | 2  | 24  |

4. Conclusions
In the hazard identification, there were three types of biological hazards, five types of chemical hazards, and seven types of physical hazards that could be met at every production process. Based on the CCP analysis with the decision tree, seven processes were included as CCP. After determining the process included as the CCP, the next phase determined the critical limit at each process. The critical limit was essential to control the excellent apple pie.

At GMP analysis, the SME was not good enough to implement GMP because several aspects could be maximized. The last step was measuring the potential failure at CCP with the FMEA method. Three potential failures have an RPN value more than a critical RPN. The monitoring system recommendation was the implementation of new rules and SOP for the production process. Check sheets also essential to control the obedience of the workers to the rules and SOP.

This study contributes to the enrichment of the references regarding risk management in food safety. With the optimization of GMP aspects in food processing, it is also expected to grow SME productivity, profitability, and business sustainability. Future studies should investigate other identical SMEs so that they can become a benchmark and a basis for determining quality standardization in this industry later.

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