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Good Manufacturing Practice (GMP) in Tofu MSMEs in North Aceh

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Abstract
This study examined tofu MSMEs in Lhokseumawe City and the North Aceh District. Observations indicate discrepancies between tofu production and the GMP requirements for Good Manufacturing Practices. The amount that the tofu sector has adopted appropriate food production procedures by the Regulation of the Ministry of Sector of the Republic of Indonesia Number 75/M-IND/PER/7/2010 is determined using a GMP approach. This research is anticipated to improve the product safety of the tofu industry and provide recommendations for improvement. In this study, data collection techniques included candid interviews related to the GMP aspect questionnaire consisting of 11 inspection aspects, direct field observation of 21 MSMEs by marking the location conditions, production equipment, and materials used, and following the processing process, followed by a search for deviations from GMP aspects and comparison with the literature review, documentation of the necessary data related to GMP assessment, and a search for relevant literature. According to the evaluation, 12 MSMEs with a value range of 41% to 60% fell into the category of not meeting the requirements. The second criterion is extremely inadequate, ranging from 21% to 40% for five MSMEs. Additionally, the criteria for sufficient completion with a range of values between 61% and 80% for up to 4 MSMEs led to an evaluation of 11 GMP aspects in 21 MSMEs. Know on the location aspect with a percentage of 71% in the sufficient category, building aspects with a percentage of 11% in the critical category, aspects of sanitation with a percentage of 40% in the category of very less fulfilling, aspects of machinery and equipment with a percentage of 80% in the category of sufficiently fulfilling, aspects of materials with a percentage of 100% in the category of fulfilling, and aspects of supervision with a percentage of 40% in the category of fulfilling.

Keywords:
Good Manufacturing Practice; Micro, Small, and Medium Enterprises;

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INTRODUCTION

Indonesia is a fertile agricultural nation with a tropical climate. Therefore, residents can take advantage of this by cultivating various plants. Soybeans are one of the local crops that is a commodity. Soybeans can be processed into various foods, including Tofu, tempeh, soy sauce, and other items and ingested directly.

According to the results of the National Socioeconomic Survey (SUSENAS) by the Central Bureau of Statistics (BPS) for 2022, the average consumption of Tofu is 7.50 kg/capita/year. The average consumption of tempeh in the same period was 7.47 kg/capita/year, and the average consumption of soy sauce was 0.70 kg/capita/year. It is predicted

that the average consumption of soybeans in the form of Tofu in 2022-2024 will be 8.02 kg/capita/year, the average consumption of tempeh in the same period is 7.70 kg/capita/year, and the average consumption of soy sauce is 0.82 kg/capita/year. Based on this, it shows that the most popular soybean-processed product is Tofu.

The high public demand for Tofu products has fostered a general interest in establishing a business processing soybeans into Tofu products because Tofu processing is relatively easy, can be processed traditionally, and can be carried out by various groups of people with limited capital and equipment, so that it can become the foundation for a source of income in improving their welfare. It can be seen from the growth of the Tofu industry, which is getting bigger.

The Food and Drug Supervisory Agency (BPOM) provides a safety assurance system aimed at the food processing sector for high-quality and safe food production, namely Good Processed Food Production Methods (CPPOB), commonly called Good Manufacturing Practice (GMP). This rule can be seen in BPOM Head Regulation Number HK.03.1.23.04.12.2207 of 2012 concerning procedures for inspecting MSME's facilities which consist of production locations and environments, buildings and facilities, production equipment, water supply or water supply facilities, hygiene and sanitation facilities and activities, employee health and hygiene, maintenance and sanitation hygiene programs, storage, process control, food labelling, supervision by the person in charge, product recall, recording and documentation, and employee training.

This research was conducted on MSMEs Tofu in Lhokseumawe and North Aceh District. Based on the results of observations that have been made, there is a discrepancy in Tofu production with GMP requirements. The GMP determines how much the Tofu industry has implemented suitable food production methods according to the Regulation of the Ministry of Industry of the Republic of Indonesia number 75 of 2010 to produce high-quality and safe Tofu for consumption. This research is expected to improve the food safety of the Tofu MSME in Lhokseumawe and North Aceh District and be able to provide suggestions on aspects to be improved.

Ergonomics studies the interaction between humans and their workplaces [1]. Industrial hygiene is an ergonomics discipline that studies how to prevent, identify, assess, and control environmental factors in the workplace that can cause deviations, health problems, and discomfort for workers and others affected by it. Hygiene behavior bad ones can be a source of disease pathogens [2]. The examination of how to foresee, comprehend, assess, and control workplace environments that could lead to illness or injury in people is known as industrial hygiene [3]. Product quality matters to *fitness for use* or suitable or suitable for use, meaning that a product of goods and services must be able to meet the needs and desires of customers [4]. Quality assurance is defined as systematic and planned activities implemented in a quality management system to provide confidence that the products and services will meet quality requirements [5]. A key component of both products and processes is quality. It is regarded as a competitive advantage for businesses and organizations [6]. The simplest definition of quality relates to how products and services are perceived or valued by their recipients, end consumers, or market [7]. Business people do not realize the importance of ergonomics and are reluctant to implement an ergonomic work environment [8]. Work environments should be designed for productivity and well-being, as these two factors are interdependent [9].

Food is essential to survival; food safety is a fundamental human right. Unsafe food puts billions of people at risk worldwide [10]. Despite recent advances in technology and knowledge, infectious illness remains a global problem [11]. Many governments have implemented health protection measures and food safety regulatory systems to combat infectious illnesses. Many food safety regulators worldwide use food safety inspection as a measure of health protection [12]. Food safety inspections can take various forms when applied at distinct stages of the food production system. The words "inspection" and "analysis" are sometimes interchangeable. In this instance, food safety inspection requires the direct analysis of a food sample to determine its composition, level of contamination, or quality. Before foods enter a consumer market or when they are being imported, this type of food safety inspection is frequently used [13]. Traditionally, food safety inspections evaluate food management practices and the condition of food production environments [14]. Consumer health and food safety are the food industry's top priorities [15]. Consumer safety and health are the first concern [16]. Therefore, the company also establishes a policy for processing its products. If safety is not observed, food can be a source of disease and death. In addition, the food produced is undoubtedly fit for consumption with the characteristics of not rotting, disgusting, and good quality. Applying guidelines for good processing practices will avoid or reduce product

contamination by biological, chemical, and physical hazards [17].

Through the Food and Drug Supervisory Agency, the Indonesian government stipulates Guidelines for Good Processed Food Production Practices (CPPOB) GMP [18]. Following the processing guidelines from GMP means trying to minimize the risk of poor quality in food processing [19][20]. The application of GMP in maintaining food safety follows the application of the *Pre-requisite* HACCP. *Pre-requisite* is a minimum procedure that must be met in all food processing processes, from the supply of raw materials to the final product related to a function, to prevent contamination due to food production or processing to produce safe products [21][22][23]. The GMP requirements stipulated in the food processing industry generally consist of 17 aspects, including location, buildings, machinery and equipment, materials, process control, final products, laboratories, employees, packaging, labels and product descriptions, storage, maintenance, and programs, sanitation, transport, training, and product recall [24].

Gap analysis is a significant step in the planning and work evaluation stages. This method is one of the most widely used methods for managing the internal management of an institution. A gap identifies a difference (*disparity*) between one thing and another [25].

Five *Why* is a structured approach that asks questions repeatedly to understand the cause of the problem and develop practical corrective actions to reduce the incidence and prevent accidents from happening again. It is a method of inquiry to explore the causal relationships underlying a problem. The investigator continues to ask the question, Why? until it achieves its objective; sometimes, additional questions are necessary or valuable because it is essential to ensure the questions are asked until the actual cause is found. Obtaining objective information or evidence at each stage of the process is usually required to get more meaningful information [26].

METHOD

This research was conducted in the Tofu MSMEs of Lhokseumawe and the North Aceh District. April to May 2023 saw the implementation of this study during two months. The owners and employees of Tofu MSME were interviewed, as well as through firsthand observations and interviews. The methods used to collect the data in this study included open discussions about the GMP aspect questionnaire, which included 11 inspection aspects, direct field observations at 21 Tofu MSMEs in Lhokseumawe and North Aceh Regency by focusing attention to the location's condition, the production equipment's condition, the materials being used, and the process being carried out, looking for deviations from the GMP aspects and comparing them to published data, documenting the data required, and reviewing the data. This study assessed 11 aspects of GMP, namely the elements of location, buildings, sanitation facilities, machinery and equipment, materials, supervision, final product, employees, packaging, storage, and maintenance.

The analysis is used to identify gaps (non-compliance) concerning GMP aspects that occur between the standards on GMP requirements and the operational processes and activities carried out by MSMEs. The results of the gap analysis assessment are then made in the form of a percentage. The percentage of this value can help evaluate the actual conditions of GMP implementation of an MSME with several indicators. The equation used to calculate the suitability level is as follows [19] :

$$Tk = \frac{\sum Xi}{\sum Yi} X\ 100\% \quad (1)$$

The results of the conformity level obtained will be included in the categories 10 % - 20 % = Critical, 21 % - 40 % = Very Inadequate, 41 % - 60 % = Inadequate, 61 % - 80 % = Enough Meet, and 81% - 100 % = Fulfill. An analysis will be conducted using the five whys method used in *Root Cause Analysis* (RCA) to find appropriate recommendations for improvements based on problems with each GMP aspect. The step of this research is described in Figure 1.

RESULTS AND DISCUSSION

General Description of SMEs

The research was conducted on 21 small and medium-sized micro-enterprises with 4 to 5 employees in each medium and small micro-enterprise. Tofu MSMEs produce between 50 kg and 250 kg of soybeans per day. Processing of Tofu is still done manually and partially automatically. The tofu SMEs made Tahu Cina and Tahu Sayur on analysis. Tahu Sayur requires particular caution during processing because of its dense texture and big pores. This Tofu is larger and extremely comparable to Tahu Cina. However, Tahu Cina has a softer feel and is more resilient.

Assessment of GMP aspects in Tofu MSMEs

Based on the results of the assessment of MSMEs in Tofu through filling out a questionnaire, the following is a recapitulation of the percentage results of the GMP assessment of MSMEs in Lhokseumawe and North Aceh District, which can be seen in Table 1.

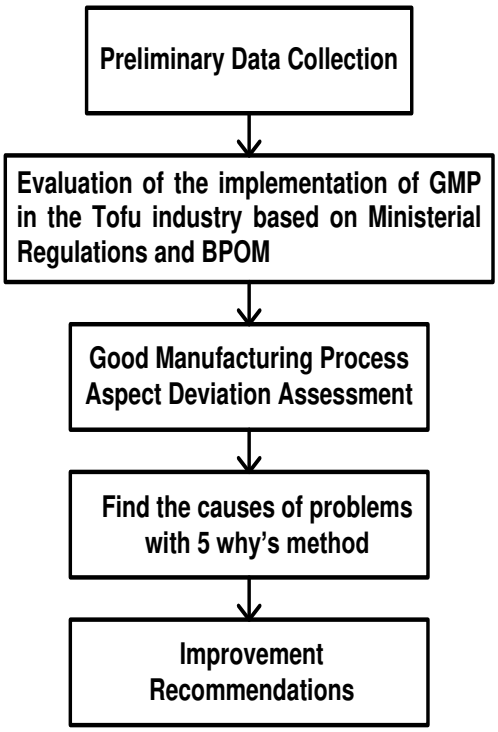

Figure 1. Flowchart Research

Table 1. GMP Assessment Percentage Summary

No.	MSMEs	Percentage (%)	Information
1	MG	56%	Less Fulfilling
2	MM	58%	Less Fulfilling
3	ZZM	67%	Enough Fulfillment
4	WHY	56%	Less Fulfilling
5	PA	63%	Enough Fulfillment
6	ZTN	60%	Less Fulfilling
7	JT	42%	Less Fulfilling
8	JIT	39%	Very Inadequate
9	MT	47%	Less Fulfilling
10	SFRN	35%	Very Inadequate
11	DOI	51%	Less Fulfilling
12	JMP	47%	Less Fulfilling
13	TM	42%	Less Fulfilling
14	MJ	47%	Less Fulfilling
15	TAS	61%	Enough Fulfillment
16	TD	51%	Less Fulfillment
17	MZ	56%	Less Fulfillment
18	IHS	40%	Very Inadequate
19	TD	40%	Very Inadequate
20	TP	33%	Very Inadequate
21	AT	67%	Enough Fulfillment

The percentage of *Good Manufacturing Practices assessment* for UMKM Tofu in the form of a histogram can be seen in Figure 2.

Based on the Table 1 and Figure 1, the results of the assessment of MSMEs in Lhokseumawe City and North Aceh District are shown. 12 MSMEs fall into the criteria of not fulfilling with a value *range of* 41%–60%. The second criterion is that it is very inadequate, with a value *range of* 21%–40% for five SMEs. Furthermore, the criteria are sufficient to meet the value *range of* 61%–80% for as many as four SMEs.

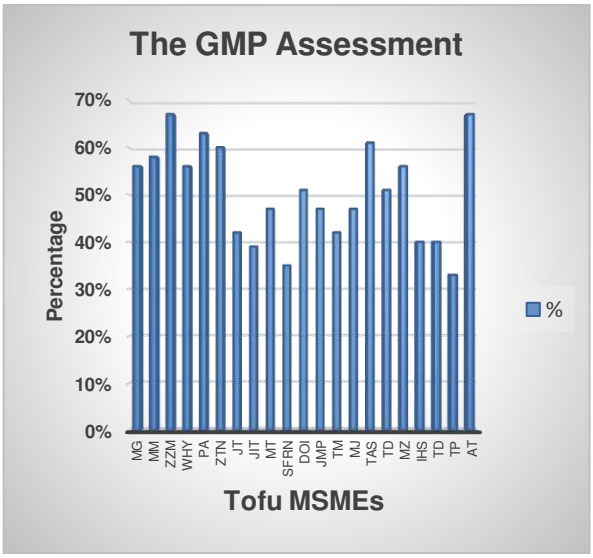

Figure 2. GMP Assessment Results

GMP Requirement Non-Conformity Assessment

Location

The locations of tofu MSMEs are generally close to privately owned farms, which are located adjacent to the tofu production site, and several other locations adjacent to the main road, making them quite vulnerable to vehicle pollution.

Building

Tofu MSMEs are very far away in the hygiene category. Factory buildings are generally built without walls, doors, windows, or ventilation. It is of particular concern because air pollution can quickly enter the production space. The meeting between wall and wall in the production area forms dead angles or does not form an indentation, making it challenging to clean. The floor in the production area is uneven or has holes and is not sloping towards the drain, so the remnants of the falling production materials become stuck.

Sanitation Facilities

The cleaning and washing facilities are directly located in the production area. Soybean washing is often done quickly so that many soybeans fall and spread to other sites. Many tofu factories do not provide toilet and hygiene facilities for employees. Therefore, employees wash their hands, change clothes, and rinse their shoes directly in the tofu production area. It has an impact on the water pollution used in tofu production.

Machinery and Equipment

Machinery and equipment used for the production process are still dirty and unkempt, and when production equipment falls to the floor or is placed in any place, it is not cleaned again when worn. Materials made of wood, such as tofu molds, are not cleaned after use when used for the following production process.

Material

Two types of materials are used for making Tofu: raw materials and additional materials. The raw materials used by Tofu MSMEs are not harmful to health and meet physical standards and requirements. It is known because the raw material used is soybean, which has its own criteria, and a physical examination is carried out to see which soybean is suitable for food processing. Meanwhile, the additional raw materials used, such as vinegar or brine to precipitate soybean starch, do not yet have a quality standard set by the minister. Vinegar used as an additional ingredient is prepared by tofu MSMEs.

Supervision

Tofu MSMEs should have a formula for determining the type of material used, the amount of material for one use, the stage of processing, and the procedure for the amount of output obtained. The company must also have a description of the use of containers, packaging, and labels and a method for checking the final results of the processing. The production process is regulated to prevent the entry of foreign materials into processed food, to keep equipment and the production floor always clean, and to store raw materials separately from the production area to maintain their quality. Employees must always supervise processes, materials, equipment, and finished products to maintain safety.

The Final Product

The final product of tofu MSMEs is only tested physically and tasted. The products have never undergone organoleptic, physical, chemical, or even biological tests, so they cannot guarantee the safety of their products with certainty.

Employee

The most critical aspect of the production process is employees, which still carry out manual and semi-automatic production processes, so employees play an essential role in the production process. They are in critical condition. It is of particular concern for the implementation of GMP. Employees should wear appropriate work clothes when doing their work. Employees in the production room must use body *equipment* such as gloves, headgear, and proper shoes to avoid physical, biological, or chemical contaminants. When carrying out the production process, employees should be able to get used to being more disciplined to be able to restrain themselves from drinking/eating, spitting, and, what is more, so that they do not smoke during the production process because these activities can create contaminants that are harmful to production and damage the safety of processed food.

Packaging

The packaging carried out at Tofu MSMEs uses containers for distribution in buckets filled with water. This situation can damage product quality which will not be able to guarantee product quality and can be dangerous for consumers because the final product will be vulnerable to contamination from outside contamination. The correct action to overcome this problem is to start packaging with a container with a lid to protect the product from environmental contamination.

Storage

Tofu MSMEs do not have storage space for raw materials, additives, and other equipment. Raw materials are usually stored at the home of the business owner, but some basic materials and additional materials are stored in the Tofu SMEs in the same place and conditions as the Tofu production site. This situation is feared to cause cross-contamination. The Tofu production room is also not free from insects and other pests because the production room has no walls and a makeshift door.

Maintenance and Sanitation Program

The machines used by tofu MSMEs in Lhokseumawe and North Aceh District are not directly related to the production process and appear poorly maintained, and the equipment used, such as tofu molds, is not cleaned for further production. The resulting solid waste is collected for resale, and some MSMEs use it as animal feed. Liquid waste from the production process is channeled into water disposal channels and immediately disposed of without being processed first.

The level of GMP implementation in tofu MSMEs in Lhokseumawe City and North Aceh District

Based on an assessment of the 11 aspects of GMP, the results show that some elements have been fulfilled, sufficiently fulfilled, not fulfilled, significantly less fulfilled, and critical. The most rating on each aspect will represent the assessment taken. The assessment results for each element can be seen in Table 2.

The assessment results showed two aspects in critical condition, three aspects in a very unsatisfactory situation, two aspects in lousy condition, three in sufficient condition, and one in fulfilling condition. Aspects in the categories of less fulfilling, significantly less fulfilling, and critical will be this study's focal point for improvement. The results of this assessment show that there are still many aspects of GMP that tofu SMEs have not implemented. There need to be improvements made to tofu MSMEs

Improvement Recommendations

The improvement recommendations are based on analyzing the non-compliant aspects of GMP. As for improvements, the recommendations in this research are as follows:

1. Establish the Standard Operating Procedure (SOP) for working clothes.
2. Establishing the Standard Operating Procedure (SOP) of manufacturing processes
3. Established the Standard Operating Procedures for cleaning and sanitation.
4. Apply the SOP and the warning poster to the production space.

Table 2. Results of GMP Aspect Assessment

No	Assessment Aspects	%	Information
1	Location	71	Enough Fulfillment
2	Building	11	Critical
3	Sanitation Facilities	40	Very Inadequate
4	Machinery & Equipment	80	Enough Fulfillment
5	Material	100	Fulfill
6	Supervision	40	Very Inadequate
7	The final product	67	Enough Fulfillment
8	Employee	0	Critical
9	Packaging	50	Less Fulfilling
10	Storage	40	Very Inadequate
11	Maintenance	57	Less Fulfilling

CONCLUSION

The assessment of MSMEs in Lhokseumawe City and North Aceh District showed that 12 were included in the criteria for not fulfilling the requirements, with a value *range of* 41%–60%. The second criterion is that it is very inadequate, with a value *range of* 21%–40% for five SMEs. Furthermore, the requirements of sufficient fulfillment with *a range* of values of 61%–80% were met by 4 SMEs, and the results of the assessment of 11 aspects of GMP were met by 21 SMEs. Know the location aspect with a percentage of 71% in the sufficient category; building aspects with a percentage of 11% in the critical category; aspects of sanitation facilities with a percentage of 40% in the category of very less fulfilling; aspects of machinery and equipment with a percentage of 80% in the category of sufficiently fulfilling; aspects of materials with a percentage of 100% in the category of fulfilling; and aspects of supervision with a percentage of 40%. In the category of very less fulfilling, product aspects finally have a percentage of 67% in the sufficiently fulfilling category, employee aspects have a percentage of 0% in the critical category, aspects of packaging have a percentage of 50% in the less fulfilling category, aspects of storage have a percentage of 40% in the very less fulfilling category, and aspects of maintenance have a percentage of 57% in the inadequate category.

The suggestions given to tofu MSMEs in Lhokseumawe City and North Aceh Regency are as follows:

a. MSMEs know they need to improve food safety with the Guidelines for Good Processed Food Production (CPPOB).
b. Improving food safety can be supported by conducting periodic evaluations using GMP guidelines.
c. It is expected that MSME is able and willing to implement the recommendations for improvement that have been given.

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