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Implementation of GMP and WISE in UMKM X in Samarinda City

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ABSTRACT

MSME are particularly dynamic, creating employment and significantly contributing to local and national economies. UMKM "X" is a MSME already has a PIRT registration. However, it still needs to meet the requirements of good food quality. GMP is the fundamental requirements that must be fulfilled if it wants to consistently produce quality and safe food products. Furthermore, UMKM "X" was caught in an unproductive work cycle. WISE need to be applied to provide a practical guidance for MSEMs to improve productivity and quality in the workplace. Therefore, this research aims to evaluate the application of GMP and WISE method in UMKM "X" and proposed improvements in the production process. The result showed that UMKM "X" has already applied GMP 51% and WISE 60% of the total requirements. In order to prioritize the improvement, AHP method was utilized. The critical elements in GMP that needed to be improved were food safety training for employees (28%). equipment maintenance for sanitation effectiveness (14%) and toilet maintenance to ensure they are covered (14%). Furthermore, WISE evaluation showed that fire hazard management (22%). Proposed improvements include installing warning signs and hygiene checklists for GMPs, and implementing SOP for fire hazard mitigation at WISE.

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1. INTRODUCTION

Micro, Small, and Medium Enterprises (MSMEs) are business activities conducted by individuals or individual entities that are not part of a company or subsidiary. MSMEs play a role in the economic and social development of a country. They are capable of expanding employment opportunities and providing broad economic services to the community [1]. The Department of Cooperatives, Small and Medium Enterprises, and Industry of Samarinda City, as stated on the Satu Data Samarinda website, reports that the growth of MSMEs in Samarinda in the years 2020-2021 was 80%, with a specific growth rate of 76% for culinary MSMEs.[2]. Food produced by MSMEs needs to obtain distribution permits to ensure that the food is safe, of high quality, and nutritious. These permits are obtained through inspections of the food production process to obtain SPP-IRT. [3]. Food safety can be achieved by meeting the requirements of Good Manufacturing Practices (GMP) for Micro, Small, and Medium Enterprises (MSMEs), which will refer to regulations issued by the Food and Drug Monitoring Agency (BPOM) Head Regulation in 2012. Efforts to meet food safety standards need to consider factors related to working conditions, including the physical conditions of employees and their environment. An approach that can be applied to ensure working conditions is Work Improvement in Small Enterprises (WISE), issued by the International Labor Organization (ILO) and adopted by the Ministry of Manpower of the Republic of Indonesia. [4].

UMKM X has been established since 2017 and produces 13 types of products, all of which are manually made by 13 employees. UMKM X already has a food distribution permit, SPP-IRT. The initial observation results indicate that UMKM X has not fully implemented GMP (Good Manufacturing Practices) and WISE (Workplace Improvement in Safety and Environment) standards. For example, they do not use personal protective equipment such as aprons, gloves, and head coverings during food production, the hygiene facilities for employees are incomplete, and the production area is dirty and dusty due to the banana smoking process. These deviations can lead to contamination of the produced food, affecting food safety. Regarding WISE deviations found at UMKM X, it includes the absence of an adequate fire hazard mitigation system. This means that in the event of a potential fire, employees are not adequately prepared to respond to the danger. This situation poses a significant risk to the safety and security of employees in the workplace.

Therefore, this research aims to assess the implementation of GMP and WISE in UMKM X and identify corrective actions for the deviations observed. These improvements can assist UMKM X in minimizing deviations, thereby enhancing the food safety of their processed products and ultimately contributing to the renewal of their food distribution permit.

Similar research studies to this one have been conducted, but there are differences in the objects of study. For instance, in the study by Wardani et al. (2018) [4] (cakes dan bread in IKM X), Suhardi dkk., (2020) [5] (Tofu in IKM Tahu Sari Murni), Miasur dkk., (2021) [6] (Tofu in Pabrik Tahu Karya Mukti Bandungan), Kurniasari dkk., (2022) [7] (Canned Gudeg in CV Buana Citra Sentosa), Pawitra dkk., (2022) [8] (Amplang in UKM Amplang Samarinda). The difference between previous research and the current study lies in the prioritization process using the Pareto principle and the use of Root Cause Analysis (RCA) to analyze the causes of deviations in the present study.

2. METHODS

GMP is a guideline for carrying out food processing according to the standards issued by the Food and Drug Administration (BPOM). Good Manufacturing Practices consists of 14 aspects that need to be observed, namely location and production environment, buildings and facilities, production equipment, water supply or water supply facilities, hygiene and sanitation facilities and activities, employee health and hygiene, maintenance and employee sanitation hygiene programs, storage, process control, food labeling, supervision by the person in charge, product distribution, recording and documentation, and employee training [9]. WISE is a guideline for assessing the suitability of OHS implementation implemented by small businesses such as the object of the current research, namely the banana chip and sanggar rimpi business produced at home. WISE can be implemented in small businesses because in practice this method is easy to do and does not require a large amount of money to run, but it is still beneficial for the implementer [10].

GMP and WISE evaluations were conducted by observation and interview. GMP inspection is conducted in 14 elements and WISE is 8 elements.

Table 1: Checklist of GMP

No	Audit Element	Nonconforming			
A	**LOCATION AND PRODUCTION ENVIRONMENT**	**MI**	**MA**	**SE**	**KR**
	Location and IRTP environment are not maintained, dirty, and dusty				
B	**BUILDING AND FACILITIES**	**MI**	**MA**	**SE**	**KR**
	The production area is narrow, difficult to clean, and is used to produce products other than food				

Source : Regulation of the Head of BPOM Number HK.03.1.23.04.12.2207 [9].

Inspection of the GMP checklist is carried out by comparing the checklist with the current conditions at UMKM X. If a non-conformance is found, a "1" will be marked in the non-conformance column. There are four levels of non-conformity, namely critical (KR), serious (SR), major (MA), and minor (MI). The first is "critical", if not met it will directly affect product safety and must be met. "Serious" level, if not fulfilled will potentially affect product safety. The "major" level, if not met will potentially affect product safety control efficiency. The "minor" level, if not met will affect product quality. The examination of the WISE checklist is carried out in several stages: (1) determine the work area, (2) make observations around the work area before filling in the checklist, (3) give a mark in the "no" or "yes" statement column. If an action requires improvement, it will be marked "✓" in the "yes" column.

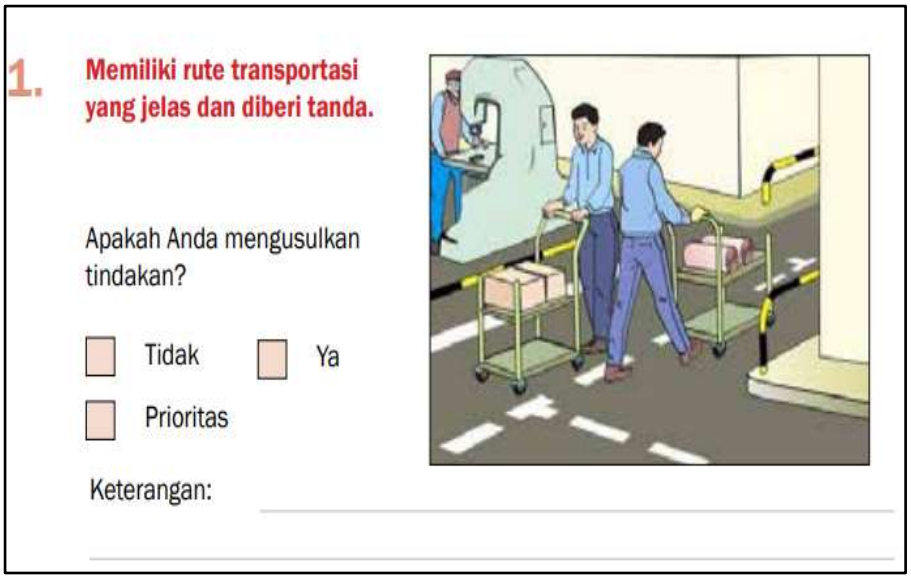

Figure 1: Checklist of WISE
Source: ILO checklist (2015).

The selection of improvement priorities is carried out using the AHP method. AHP is a decision-making process using pairwise comparisons. The basic principles of AHP are creating a hierarchy to arrange elements to simplify problems, assessing criteria to express opinions on a scale of 1 to 9, determining priorities is the result of relative comparison of all criteria so that weights and priorities are produced, and logical consistency [11]. The formula used in the AHP method is:

$$CI = \frac{\lambda_{Maksimum-n}}{n-1} \quad \text{---------- (1)}$$

Note:

CI = Consistency Index
$\lambda_{Maksimum}$ =The largest eigenvalue

$$CR = \frac{CI}{RI} \quad \text{---------- (2)}$$

Note:

RI = Random index
Jika, CR ≤ 0,1, so result are consistent

The results of the weight value will be prioritized using the pareto principle. The pareto principle is known as the 80-20 rule which states that 80% of problems come from 20% of causes. The calculation results will be depicted in a pareto diagram [12]. Proposed improvements are made to the 20% priority deviations. Analysis will be performed on the priority deviations using the 5 why tool with the Root Cause Analysis (RCA) method. RCA will help discover why an event or failure occurred. Identifying why the event occurred will help determine corrective action [13].

3. RESULTS AND DISCUSSION

3.1 GMP Checklist Check in UMXM X

The inspection results on the GMP checklist show 18 nonconforming elements. The 18 elements consisted of 5 critical, 10 serious, 2 major, and 1 minor of nonconforming. You can find the details of the nonconforming findings in **Table 2**.

Table 2 Nonconformance of GMP checklist

Element	Explanation	Evidence
	Critical Level	
No covered garbage disposal	Closed trash bins are not available and the waste management system is done by burning.	
	Serious Level	
Floors, walls, and ceilings, unkempt, dirty, dusty, and or slimy	The floor was dirty due to banana sap, the walls were dirty due to smoke dust, and there were cobwebs around the production room.	
	Major level	
Washing chemicals not handled and used according to procedures, stored in unlabeled containers	The washing chemical used is cream soap for equipment. Soap is simply placed on the floor without a container and label.	
	Minor Level	
Production documents are not up-to-date, not accurate, not traceable and not kept for 2 (two) times the shelf life of the food products produced.	There are no production documents in UMKM X, so all types of records are not kept within 2 times the production shelf life.	-

Based on the GMP inspection results, the compliance percentage with GMP in UMKM X is 51%. Here are the details of the GMP implementation results in UMKM X.

Table 3: The implementation of GMP

No	Elements	Total Elements	Number of Deviations			
			Minor	Mayor	Serious	Critical
1	Location and Production Environment	1	-	-	1	-
2	Building and Facilities	3	-	1	2	-
3	Production Equipment	3	-	-	1	-
4	Water Supply or Water Source	2	-	-	-	-
5	Hygiene and Sanitation Facilities and Activities	4	-	-	2	1
6	Employee Health and Hygiene	5	-	-	1	1
7	Maintenance and Hygiene and Sanitation Program	4	-	1	1	-
8	Storage	2	-	-	-	2
9	Process Control	5	-	-	1	-
10	Food Labelling	2	-	-	-	-
11	Supervision by Responsible Person	2	-	-	-	-
12	Product Withdrawal	1	-	-	-	-
13	Record and Documentation	2	1	-	1	-
14	Employee Training	1	-	-	-	1
Total		**37**	**1**	**2**	**10**	**5**
Implementation of GMP (%)		**51%**				
IRTP Level		**IV**				

3.2 Examination of the WISE Checklist

The inspection results on the WISE checklist indicate that 23 elements from 8 aspects require improvement. The deviations consist of 3 elements in material storage and handling, 1 element in workplace design, 1 element in productive machinery safety, 5 elements in physical environment, 1 element in electrical hazard protection, 8 elements in fire hazard prevention, 3 elements in welfare facilities, and 1 element in work organization. Based on the findings of deviations, the application of the WISE checklist is 60%. Several deviations can be seen in **Table 4**.

Table 4: Nonconformance of WISE checklist

Element	Explanation	Evidence
Fire hazard mitigation	There is no training for employees to extinguish fires, even though there have been 2 potential fires caused by gas leaks during the frying process	
Physical environment	There is no partition to protect the product from sunlight, which will affect the product. There is no use of local exhaust for combustion fumes.	
Work-station design	There are no shelves to store cooking utensils, the utensils are only placed in the production area without a cover.	

Based on the result of the WISE examination in UMKM X, the percentage of WISE compliance is 60%.

Table 5: The implementation of WISE

No	Aspek	Total Elemen	Usulan Tindakan Perbaikan	
			Ya	Tidak
1	Material storage and handling	10	3	7
2	Work-station design	10	1	9
3	Productive machine safety	4	1	3
4	Physical environment	9	5	4
5	Electrical hazard potential	9	1	8
6	Fire hazard mitigation	9	8	1
7	Welfare facility	5	3	2
8	Work organization	2	1	1
Total		**58**	**23**	**35**
Implementation of WISE (%)		**60%**		

3.3 Result of Improvement Priorities

Priority weights are calculated for each deviation found. The first step if create a hierarchy structure to demonstrate the relationship between deviations from GMP and WISE elements and aspects. The second step is to prepare a paired comparison assessment questionnaire. The third step is to calculate priority weights. The fourth step is to measure consistency. Finally, prioritization of deviating elements in GMP and WISE is done using a Pareto diagram.

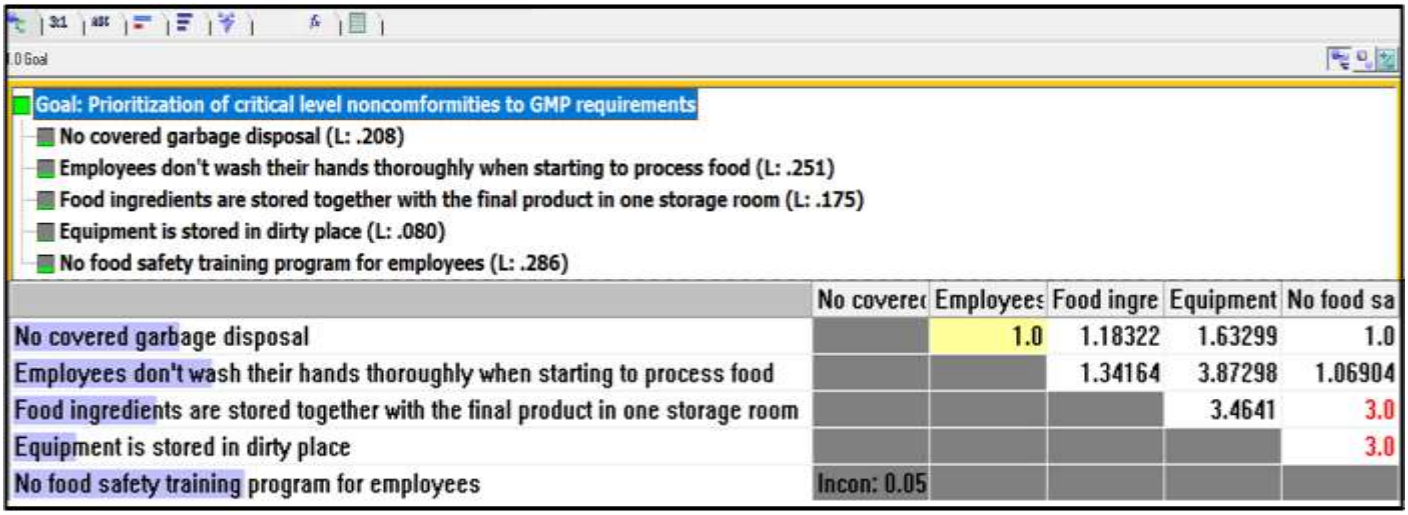

Figure 2: The calculation of priority weights and consistency testing

AHP calculations are carried out using Expert Choice software to determine priorities for GMP and WISE deviations. Prioritization of each GMP and WSE deviation is determined using a Pareto diagram to identify the top 20% of deviations considered most important for improvement. Below is one the priority results using the Pareto diagram.

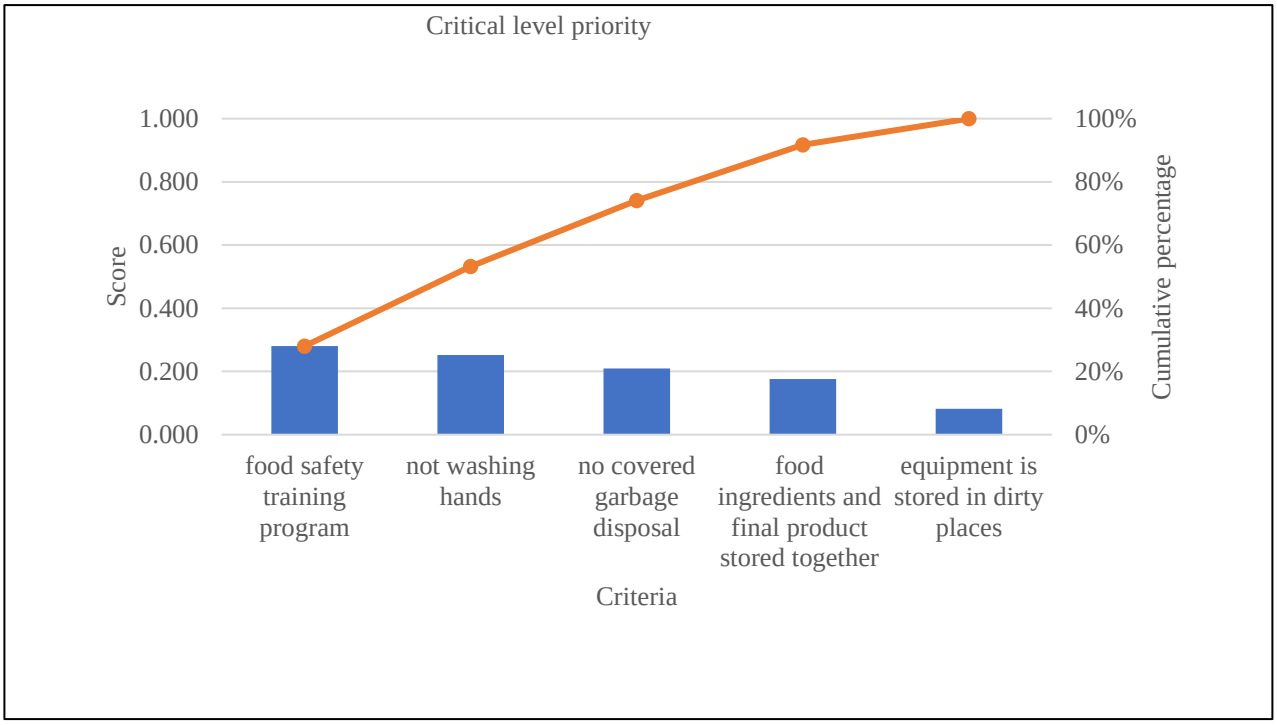

Figure 3: The Pareto diagram

The Pareto diagram will determine the top 20% of deviations that are most important to address compared to the remaining 80% of deviations. The deviations included in the top 20% for improvement are determined based on their priority weight values. Improvement recommendations will be proposed for these deviations.

Table 6: The priority of GMP and WISE deviations

Standar	Kriteria	Prioritas
GMP	**Critical level** 1. IRTP does not have food safety training program for employees.	**28%**
	Serious level 1. Equipment is not maintained, is in a dirty condition, and does not guarantee effective sanitation, and 2. Toilets or latrines are dirty and not well-maintained and they are open to the production area.	**28%**
WISE	1. Ensuring the existence of emergency response procedures.	**22%**

3.4 Proposed Improvement

The proposed improvements regarding the identified deviations were determined by conducting an analysis using the 5 Whys tool within the Root Cause Analysis method. For deviations deemed critical, warning signs are provided to enhance awareness of the importance of maintaining cleanliness, primarily through employee awareness campaigns. Similar improvements were also implemented in the studies referenced in [5], [6], dan [14].

(a) (b)

Figure 4: Warning sign
Source: (Miasur dkk., 2021) [6]

For serious level improvement, a storage cabinet was constructed to store equipment [6] and a cleanliness monitoring table was created to assist business owners in overseeing the implementation of hygiene and sanitation programs. The cleanliness monitoring table includes a schedule for regularly cleaning the production area and other activities related to hygiene and sanitation [15].

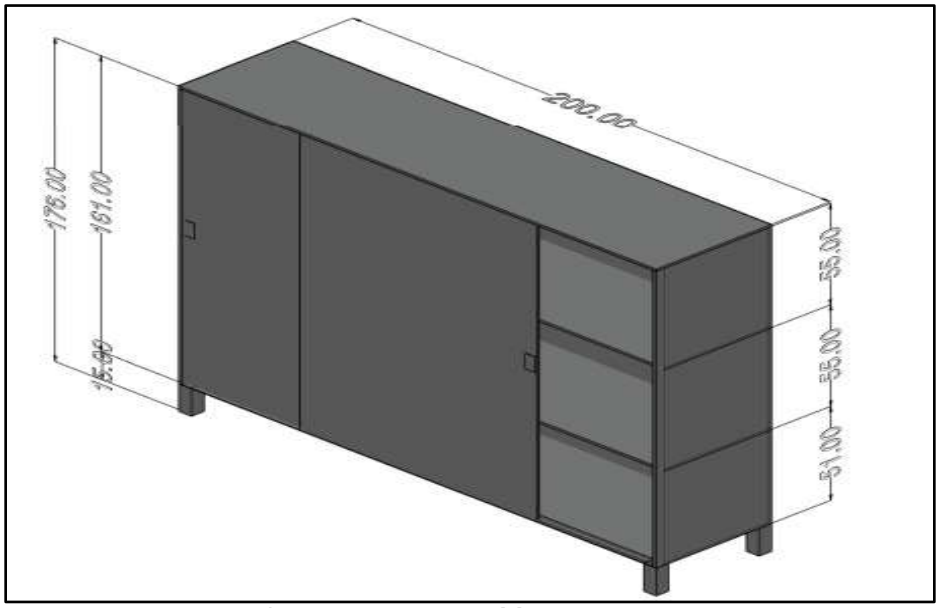

Figure 5: **Storage cabinet**

For improvements regarding WISE deviations, an emergency response procedure was established at UMKM X to address potential fires in the work area. The implementation of emergency response procedures was also conducted in the study referenced in [16]. he proposed improvement of emergency response procedures at UMKM X will follow the format outlined in the SOP (Standard Operating Procedure) writing guidelines provided by ISO/TR 10013:2001, titled "Guidelines for quality management system documentations" [16].

Table 7: **Summary of improvement**

Deviations	Improvement
Good Manufacturing Practices	
IRTP does not have food safety training program for employees.	Affixing food safety warning signs
Equipment is not maintained, is in a dirty condition, and does not guarantee effective sanitation	Storage cabinet design
Toilets or latrines are dirty and not well-maintained and they are open to the production area	Cleanliness monitoring table
Work Improvement in Small Enterprises	
Ensuring the existence of emergency response procedures	Fire hazard mitigation SOP

4. CONCLUSIONS

The results of the GMP application are 51%, and for WISE, it's 60%. Based on the weight calculation using AHP and Pareto diagram to determine improvement priorities, the priority for critical-level GMP deviations is that IRTP does not have a food safety training program for employees (28%). At the serious level, equipment not being properly maintained, in a dirty condition, and not ensuring effective sanitation (14%) and open toilets to the production area (14%) are identified, resulting in a total weight of 28% for serious deviations. The priority for WISE deviations is in the fire hazard mitigation criteria, specifically the sub-criterion of improving fire hazard mitigation (22%). The improvements recommended for critical-level GMP deviations are to provide warning signs to increase employee awareness of cleanliness. For serious-level GMP deviations, the recommendation is to design a storage cabinet and create a cleanliness monitoring table. Finally, the improvement for WISE deviations involves providing a Fire Hazard Mitigation SOP (Standard Operating Procedure).

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