**ABSTRACT**

**Background:** Good Manufacturing Practice (GMP) is a reference that explains the procedures to produce processed food so that it is of high quality, safe, and suitable for public consumption. The Food Safety Facilitator's role is to help register the processed products of SME (Small Medium Enterprise) X to obtain an NIE (Nomor Izin Edar) number.

**Objectives:** The SME assistance aims to improve the implementation of GMP so that it can meet the GMP level that meets the requirements of the Regulation of the Head of the Food and Drug Administration on Guidelines for Inspection of Processed Food Production Facilities.
INTRODUCTION

Food is one of the basic human needs. Humans are entitled to safe and quality food because it is one of their human rights. It is our obligation as food producers to produce safe and quality food for the community. Based on data on food poisoning cases reported through the Extraordinary Event Poisoning Community Information Reporting System (Sistem Pelaporan Informasi Masyarakat Keracunan dan Kejadian Luar Biasa) application, there are 6,205 data on poisoning cases in Indonesia. The presence of food poisoning cases is a sign that more attention is needed regarding food safety so that consumers are protected from health problems caused by unsafe food (Badan POM RI, 2019a).

According to the Minister of Cooperatives and Small and Medium Enterprises, until May 2022 there were 19 million Micro Small and Medium Enterprises (MSMEs) in Indonesia entering the digital ecosystem. From 2018-2023 until March, there have been 279,703 processed food MSMEs that have obtained a Distribution License Number (Nomor Izin Edar) for their processed products from the POM (Badan POM RI, 2023). MSMEs have an important role in supporting the economy in Indonesia. MSMEs are a form of productive business owned by individuals or business entities that fall under the criteria of micro businesses. There are several fields of MSMEs in Indonesia, one of which is MSMEs in the processed food sector. Processed food MSMEs are most in demand from both the elderly and the young. Processed food MSMEs have a high market share domestically and abroad. This is because people need food intake to fulfill their daily needs. In circulating food and beverage products produced by SMEs (Small Medium Enterprises) an NIE number published by the Food and Drug Supervisory Agency (Badan Pengawas Obat dan Makanan) is required. Based on Law No. 18/2012 on Food and Government Regulation No. 86/2019 on Food Safety, it is stated that every processed food produced domestically or imported for sale in retail packaging must have an NIE number.

BPOM will screen which SME products will then be given a license number. Products produced by SMEs must be guaranteed food quality and food safety from upstream to downstream, from farmers to consumers. Based on the Decree of the Head of the Food and Drug Supervisory Agency Number HK.02.02.1.2.01.22.63 of 2022 concerning Guidelines for Inspection of Processed Food Production Facilities, 25 aspects of requirements can be used as a reference in producing processed food in the category of Internal Food that is safe and suitable for distribution and consumption by the public. Aspects of the requirements in the Good Manufacturing Practice (GMP) include owner commitment, location, building, waste handling, machinery and equipment, sanitation program, materials, process supervision, final product, laboratory, pest control, employee facilities and hygiene, packaging, product labeling and description, product recall, storage, transportation, and food safety emergency response.

Contaminants are unwanted materials in food that may come from the environment or as a result of the food production process, can be biological, chemical, and foreign contaminants that can interfere with, harm, and endanger human health (Badan POM RI, 2019b). Food contamination is caused by several factors, namely biological factors, physical factors, and chemical factors. Biological factor contamination is the contamination of food caused by pathogenic bacteria that can harm and endanger human health. Microbiological hazards are pathogenic bacteria, viruses, and parasites that can cause disease or poisoning in humans (Fitriana, Kurniawan and Siregar, 2020). Examples of microbiological hazards are *Escherichia coli* and *Salmonella* sp., *Staphylococcus aureus*, *Klebsiella* sp., *Proteus* sp., *Shigella* sp., *Bacillus* sp., and *Clostridium*. Biological hazards can pose a risk of pathogen contamination of equipment, risk of food contamination by pathogens from equipment, and risk of disease transmission between humans (Christiva, Rusmiati and Setiawan, 2020). Physical factor contamination is an object that should not be present in food, for example, hair, nails, dead insects, and so on.
stones, gravel, broken glass and glass, staples, and others. These objects when entering the body can injure the esophagus and stomach or break teeth (Badan POM RI, 2019a). Chemical factor contamination is contamination derived from chemical elements or compounds that can harm and endanger human health. Examples of chemical contaminants include Aflatoxin, Cadmium (Cd), Lead (Pb), Mercury (Hg), and Arsenic (As) (Badan POM RI, 2012). These contaminants can come from the raw materials used, processing, and packaging equipment and due to processing processes, such as steaming, boiling, stir-frying, frying, roasting, and grilling (Putri et al., 2020). Chemical contamination of food products can harm human health (Pradianti et al., 2019).

BPOM in collaboration with the Ministry of Education, Culture, Research, and Technology created the “Pangan Aman Goes to Campus (PAGC)” Program. The program aims to increase student participation and competence in the field of food safety. The role of students in this program is as food safety facilitators who act as mentors for processed food SMEs. This program is a commitment to processed food SMEs with the target of more and more SME food products that meet food safety requirements to obtain an NIE number (Badan POM RI, 2022). The role of students as food safety facilitators are to provide assistance and training to SMEs. The assisted SMEs will receive assistance and training related to the implementation of GMP to register their products to obtain an NIE number.

One of the SMEs located in Sidoarjo Regency is an SME that produces frozen meat-filled kebabs. SME X is owned by a father who is around 40 years old. In carrying out the production process, SME X has 2 (two) permanent employees and recruits one additional employee if there are orders from outside parties. SME X was established in 2020 with its main activity being meat-filled frozen kebabs. Initially, the marketing of this meat-filled frozen kebab product was only to neighbors and close relatives so that orders were not too many. Over time, SME X marketed its products online using one of the e-commerce platforms. Since being marketed through online ordering, the meat-filled frozen kebabs have been in great demand from the public. The owner of SME X felt that this frozen meat-filled kebab product was in demand by the public, so the business owner took the initiative to register his product so that it had higher competitiveness and could be trusted by the public.

Meat-filled frozen kebab products are frozen processed food products that are produced by freezing and maintaining the product in a frozen state at a minimum temperature of -18°C during the distribution and storage chain. The storage process by freezing at a minimum temperature of -18°C is one of the storage methods to extend the shelf life of the product. This freezing process can inhibit microbial growth, enzymatic, and chemical reactions so that the product remains safe for distribution. To maintain the cold chain, both types of frozen processed food and ready-to-eat processed food must fulfill Good Manufacturing Practices (GMP) (Badan POM RI, 2021).

Processed foods derived from animals such as meat, milk, eggs, and other preparations become a medium for microbial growth which causes the product to spoil easily. Common bacteria in animal products are Escherichia coli and Salmonella (Noviana and Ruhban, 2020). Escherichia coli is a bacterium that resides in the human intestinal tract and is excreted through feces. Escherichia coli bacteria in the human colon play a role in inhibiting the growth of bad bacteria and as intestinal microbiota that supports the decay process of food debris in the colon (Kementerian Kesehatan RI, 2022). However, there are types of Escherichia coli bacteria that are harmful to the body, namely Shiga toxin-producing coli (STEC), Enterotoxigenic coli (ETEC), Enteropathogenic coli (EPEC), Enteraggregative coli (EAEC), Enteroaggregative coli (EIEC), and Diffusely adherent coli (DAEC). In general, harmful Escherichia coli bacteria can enter the body by consuming contaminated food or drinks. While Salmonella bacteria are bacteria that can cause infection when they enter the body called salmonellosis (Noviana and Ruhban, 2020).

Meat-filled frozen kebab products produced by SME X are one of the products that are required to have an NIE number from the BPOM because the product is a processed food product that is stored at a minimum freezing temperature of -18°C and has a shelf life of more than 7 (seven) days so that it is included in the category of Deep Food (MD). SME X with a processed meat-filled frozen kebab product intends to register its product to obtain a BPOM MD NIE number so it requires facilities, facilities, and several related documents to meet the 25 aspects of GMP requirements. Therefore, the mentoring activities carried out by this food safety facilitator can help SME X in implementing GMP to obtain an NIE number for its processed products (Badan POM RI, 2021).

METHOD

Assistance to SMEs in the application of GMP consists of several stages, namely visits and inspection of SMEs, observation of the application of GMP, determination of the value of the application of GMP, assistance, and training of GMP requirements that have not been met and then the final observation of the application of GMP. The visit to SME X was conducted three times. The first visit was to observe the application of GMP that had been carried out by SME X, then record and assess aspects that were not by the reference to the Decree of the Head of the Food and Drug Administration...
Number HK.02.02.1.2.01.22.63 of 2022 concerning Guidelines for Inspection of Processed Food Production Facilities. The second visit evaluates improvements in several aspects that do not follow the recording and assessment during the first visit. The third visit evaluated improvements to the non-conforming aspects and provided training for the employees of SME X aimed at increasing the knowledge of SME X employees. The training was given in the form of a lecture followed by a discussion and questions and answers. The material provided during the training was related to the application of Good Manufacturing Practices (GMP). Assistance is carried out by providing guidance and direction on aspects that are not following the GMP requirements so that the GMP audit assessment of SME X meets the requirements for obtaining the Distribution License Number (NIE). Assistance activities are carried out until the NIE number is published.

RESULT AND DISCUSSION

Implementation of GMP

The Good Manufacturing Practice or commonly abbreviated as GMP is one of the references that explain how processed food production is carried out so that producers can provide quality products that are safe, suitable for circulation, and suitable for consumption by the public (Zubir, Hasni and Nilda, 2022). GMP is a procedure for conducting good production, including procedures for implementing, controlling, and supervising the implementation of the production process (Purwandari, 2021). The implementation of GMP in a processed food producer has the advantage of gaining the trust of potential customers, providing quality products that are safe, suitable for distribution and consumption by the public. Processed food producers who have met the GMP requirements and have a BPOM or Special License for Home Food Industry (P-IRT number) will receive a certification that is valid for 5 (five) years.

The observations made during the assistance were based on one regulation, namely the Decree of the Head of the Food and Drug Administration Number HK.02.02.1.2.01.22.63 of 2022 concerning Guidelines for Inspection of Processed Food Production Facilities. The regulation states that there are three categories of non-conformities to CPPOB aspects, namely minor, major, and critical. Minor non-conformities are non-conformities to CPPOB requirements that, if not fulfilled, have less potential to affect product safety. Major non-conformities are non-conformities to CPPOB requirements that, if not fulfilled, have the potential to affect product safety. Critical non-conformities are non-conformities to CPPOB requirements that, if not met, could directly affect product safety.

The first visit was conducted by the food safety facilitator team together with the BPOM team. The first visit was to monitor the implementation of GMP at SME X using an assessment format from BPOM. From the visit, the non-compliant aspects of GMP can be seen in Table 1. The results of the first visit showed that the implementation of GMP at SME X had not been maximized and received a grade of D or very poor.

Table 1. Result of Observation of UKM X

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Description</th>
<th>Non-conformance Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Building construction and layout</td>
<td>The roof ceiling is peeling off</td>
<td>Minor</td>
</tr>
<tr>
<td></td>
<td>Production room doors open inward without curtains</td>
<td>Minor</td>
</tr>
<tr>
<td></td>
<td>Window without screen</td>
<td>Minor</td>
</tr>
<tr>
<td>Hygiene and sanitation facilities and activities</td>
<td>Bins do not have lids</td>
<td>Minor</td>
</tr>
<tr>
<td>Materials and storage</td>
<td>Raw materials and final products are not separated in the freezer</td>
<td>Major</td>
</tr>
<tr>
<td></td>
<td>Packaging materials are placed on the floor</td>
<td>Minor</td>
</tr>
<tr>
<td>Process control</td>
<td>There are no process control documents that are carried out consistently</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>No process control monitoring records</td>
<td>Major</td>
</tr>
<tr>
<td></td>
<td>No final product evaluation process</td>
<td>Major</td>
</tr>
<tr>
<td></td>
<td>No cross-contamination prevention and control program</td>
<td>Major</td>
</tr>
<tr>
<td>Product recall</td>
<td>No recall procedure for non-compliment products</td>
<td>Major</td>
</tr>
<tr>
<td>Pest control</td>
<td>No effort in pest control</td>
<td>Major</td>
</tr>
<tr>
<td>Employee facilities and personnel hygiene</td>
<td>No place for work clothes</td>
<td>Minor</td>
</tr>
<tr>
<td></td>
<td>No employee health check records</td>
<td>Minor</td>
</tr>
<tr>
<td>Employee training</td>
<td>No employee training program and records</td>
<td>Major</td>
</tr>
<tr>
<td>Product labeling</td>
<td>No production code and expired date on product labels</td>
<td>Critical</td>
</tr>
</tbody>
</table>
The first visit was to make initial observations of SME X. The observations made were to check the application of GMP that has been carried out by SME X using the reference of the Decree of the Head of the Food and Drug Administration Number HK.02.02.1.2.01.22.63 of 2022 on Guidelines for Inspection of Processed Food Production Facilities which contains 25 GMP aspects. The food safety facilitator will note which parts are not by the GMP parameters using the gap assessment matrix. The matrix lists the condition of the SME before improvement, the improvement suggestions given by the food safety facilitator, and the condition of the SME after improvement. The improvement suggestions given by the food safety facilitator must consider the costs that are likely to be incurred and not burden the owner of SME X. The existence of a gap assessment matrix can help SME X to improve its condition before improvement. The existence of a gap assessment matrix can help SME X in improving SME facilities that are not following the 25 aspects of GMP.

First Observation of SMEs

During the first visit, there were several findings on the construction and layout aspects of the building that did not comply with the GMP aspects. The first finding was that the roof ceiling layer in the production room was peeling off. This could cause small pieces of debris from the ceiling to fall and enter the food. Physical contamination of food can reduce the quality of food produced. The method suggested by the facilitator to the owner of SME X is to repaint and re-coat the peeling part. This method is the easiest way and does not require a long time. The next finding is that there is a production room door that is always open but not equipped with a screen curtain. In addition, there are windows in the production room that are open but not equipped with screens. The gauze installed on the windows and doors of the production room serves to prevent biological contamination in the form of insects or pests from entering the production room.

In addition to the construction and layout of the building, assistance was also provided with hygiene and sanitation facilities and activities. During the initial visit to SME X found trash bins that did not have covers. The trash can cover serves to avoid odors that cause insects or pests to enter the production room. The method suggested by the food safety facilitator to the owner of SME X is to put a lid on the trash and require it to be disposed of after each production process. More attention is needed to employee sanitation and hygiene to prevent contamination of pathogenic microorganisms or cross-contamination originating from employees (Roseno, Widyastwi, and Sudaryat, 2021).

It is necessary to pay attention to the method and place of storage of the materials used for the production process and the packaging used. During the first visit, it was found that there was a mixing of raw material storage and final product results in the freezer. Based on the regulation of the Decree of the Head of the Food and Drug Administration Number HK.02.02.1.2.01.22.63 of 2022 concerning Guidelines for Inspection of Processed Food Production Facilities, raw materials must be stored according to type and separate from the finished product. This is being done to prevent cross-contamination between raw materials and finished products. There was also a non-conformity found in the packaging material, where the packaging material was placed on the floor without a mat. The advice given by the food safety facilitator is to provide a partition in the freezer as a separator between raw materials and finished products and recommend putting product packaging materials into a special shelf for packaging materials. The special shelf for packaging materials can be filled with plastic product packaging along with product labels. The completeness of documents owned by SME X is still very lacking. This is evidenced by the absence of documents about the production process as a whole and in detail starting from the receipt of raw materials to the final product. The required documents are related to the description of general product characteristics, the use of raw materials, how they are packaged and distributed, storage, and expiration dates. For the production process to meet food safety requirements, this procedure must be carried out consistently, especially in controlling critical stages. Critical stages are stages in a processing process that require careful monitoring and supervision. Uncontrolled critical stages can result in health hazards. Critical stage monitoring must be carried out by competent personnel with appropriate backgrounds and education.

One of the next must-have documents in an SME is to have a product recall procedure. The product withdrawal procedure is related to the traceability system. Facilitate the traceability system, it can be done by giving the identity of raw materials, packaging materials, and final products. The traceability system along with product recalls must be implemented effectively if there is a final product that does not match the product characteristics set by the SME. The food safety facilitator team assisted in the preparation of the necessary documents, of course, with discussions with the owner of SME X so that the SME owner understands the purpose and content of the documents. A good and complete recording process can prevent poor quality production results because good and complete records will produce quality raw materials and final products that meet standards and facilitate the process of traceability of products that have been distributed (Wijayanti, Pramono and Dharmawan, 2022).

SME industries must have a regularly scheduled pest control program. Pest control efforts
are carried out to prevent the presence of pests in the production environment including controlling animals that may enter the production environment. On the first visit to SME X, SME X had not made any pest control efforts. This was evidenced by the absence of pest controls such as rat traps, insect traps, or the use of pesticides. The presence of pests in the production environment must be prevented by good handling so as not to contaminate the food being produced. One of the pest control programs that can be carried out to prevent the possibility of pest attacks is to carry out a good sanitation program. With the implementation of good sanitation, the production environment will be kept clean so as not to invite pests. The food safety facilitator team suggested providing mouse traps near the sink and the production entrance.

All employees entering the production room must be physically and mentally healthy and wear clean work clothes. During the first visit to SME X, employees were healthy and wearing clean work clothes. However, what was not in line with CPPOB aspects was the absence of employee health check records and no place for work clothes. SME owners should have employee health records to prevent employees who are known to have diseases that might contaminate products. Employee health records include a schedule of health checks and follow-up on the results of employee checks. It also includes reports on when employees are sick or have work accidents.

Employee training is an important aspect of implementing GMP. During the establishment of SME X, the owner said that he only conducted training for employees when they first entered the workplace without any records or documentation. This does not follow the GMP aspect which states that employee training is given to every employee covering the basic processing, hygiene, and sanitation as well as the application of Good Manufacturing Practices (GMP). Internal training can include briefings, socialization, and food safety policies on an ongoing basis. Records of employee training should be well documented.

Product labeling on food packaging circulating in the market must comply with the provisions of the NA-DPC Regulation No. 31/2018 on processed food labels. Food product labels must use the Indonesian language and at least contain information on product name, composition, net weight, production name and address, halal information, production date and code, expiration date, NIE number, and origin of food ingredients. The food safety facilitator team assisted in the design of the product label, which of course was also discussed with the SME owner because, after all, this design will be used to identify SME X products.

**SME Training and Assistance**

Training related to the implementation of GMP was conducted in stages with various materials. The training was given to SME owners and all employees by way of an explanation followed by a question-and-answer session. The material provided is related to all elements included in the application of GMP. The material presented is very important, especially for the food products produced to be safe and of high quality. Training to employees and SME owners aims to increase knowledge to employees and SME owners about the application of GMP and the importance of applying GMP in producing food products. This is in line with research conducted by (Kesuma, Rahmadianto and Yuniati, 2020) that training activities can increase employee understanding of food safety. Likewise, assistance was also carried out by (Wijayanti, Pramono and Dharmawan, 2022) that the results of community service in the form of assistance in the application of GMP are an increase in understanding and awareness of the importance of GMP from SMEs.

Assistance is carried out when making improvements to the application of CPPOB aspects that are still not appropriate. Assistance is carried out by improving CPPOB aspects such as building construction, sanitation hygiene facilities and activities, raw materials, and storage, documents related to processing control, procedures related to the withdrawal of non-conforming products, pest control, employee facilities, and personnel hygiene, traceability and recall systems, product label design improvements, and food safety emergency response procedures. The non-conformity of these aspects is classified as minor, major, and critical which can reduce the value of SME X’s CPPOB implementation.

At the end of the food safety facilitator team’s activities, SME X had made improvements to aspects that were not in line with GMP aspects. This is evidenced by the results of the evaluation of the improvement of non-compliant aspects during the third visit. The improvement process at SME X facilities only takes a short time, namely only one month. This is done because the owner of SME X wants to immediately get a distribution license number for his product so that his product is more trusted by the public. This is in line with research conducted that products that have an NIE number gain more consumer confidence and have a wider marketing network such as selling them to supermarkets (Epriliyana, 2019).

The training and mentoring activities provided good results, namely that SME X obtained an NIE number for the products produced so that it could circulate its products more widely and be more trusted by the public. The NIE number was given by the BPOM after re-auditing. In addition to obtaining an NIE number, this activity also provides increased knowledge to employees of UKM X related to GMP,
so that the products produced can be guaranteed safety. As a food safety facilitator, SME X hopes to remain consistent in implementing GMP in producing its processed products.

CONCLUSION

The results of the gap assessment matrix conducted during the first visit observation SME X has several components that do not follow the CPPOB requirements. With several non-conformities obtained, SME X received a grade of D or very poor, so it needs improvement to get an NIE number from BPOM. Within one month, SME X has been able to improve all aspects of non-conformity so that it can successfully obtain an NIE number for its products so that the marketing network is wider and more trusted by the public. Community service activities in the form of training and mentoring to the community help in the Indonesian economic system at the SME scale.

Acknowledgement

As a food safety facilitator, we would like to thank the Food and Drug Monitoring Agency (BPOM) and the Ministry of Education, Culture, Research, and Technology for organizing the implementation of community empowerment.

REFERENCES


Badan POM RI (2019b) Penerapan Peraturan Badan POM tentang Cemaran Mikroba dalam Pangan Olahan.


Badan POM RI (2023) ‘Cek Produk BPOM - BPOM RI’. Available at: https://cekbpm.pom.go.id/


Available at: https://doi.org/10.15578/JPBKPV14I1.560.


