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Development of halal assurance system for shoyu production

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A B S T R A C T

Muslim population in Indonesia was predicted to reach 214 million by 2019, making it a lucrative market from a business perspective. Muslims have the right to obtain and consume halal food products. Food and beverages must be manufactured from raw halal materials and processed in a manner that retains halal status. For instance, shoyu, a Japanese soy sauce widely consumed by Indonesians, traditionally contains a mixture of wheat and soybean fermented in two stages. Non-halal soy sauce may contain brewery or khamr alcohol and pork-derived substances as flavoring ingredients. Therefore, halal assurance system (HAS) 23000 was developed by LPPOM MUI (Food, Drug and Cosmetic Research Institute of Indonesian Ulema Council) and aimed at ensuring a product is free from contamination by haram or najis. HAS development for halal shoyu product line at Kamada Soy Sauce Inc. included conducting a preliminary audit using the gap analysis method. The development was considered complete once all 11 principles of HAS 23000 had been fulfilled. A post-audit was then performed using the same gap analysis method to compare the conditions before and after development. Subsequently, a risk analysis using failure mode and effect analysis (FMEA) was performed based on audit results and brainstorming sessions with the company. Construction of a fishbone diagram was carried out using the calculated risk probability number during FMEA risk analysis.

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1 Introduction

In 2000, Indonesia's population was 206 million and grew to 265 million by 2018 (BPS 2019). Furthermore, it is estimated that Muslim population in Indonesia was around 214 million in 2019. This demographic represents a significant market share from a business perspective because Muslims are entitled to consume halal food products, as mandated by religious beliefs. Surah Al-Baqarah 168 of the Qur'an instructs Muslims as follows:
"O people! Eat of what is lawful and good on earth, and do not follow the footsteps of Satan. He is to you an open enemy."
This directive underscores the importance of consuming food and beverages with halal raw materials and processed in a manner that guarantees the halal status.

The considerable potential in halal market segment has driven multinational companies to invest in this area (Alserhan 2010). Halal certification not only guarantees compliance with religious requirements but also significantly boosts consumer confidence by ensuring that products meet strict safety, hygiene, and quality standards. This opens up new market opportunities, allowing businesses to reach the vast Muslim consumer base locally and internationally.

Globalization has inevitably impacted the food sector, leading to an influx of foreign food products into the Indonesian market. Indonesian consumers have responded positively to these imports, including shoyu, a type of soy sauce that originates from Japan. Shoyu is a traditional Japanese condiment made primarily from fermented soybean, wheat, salt, and water. The fermentation process typically includes two stages. These include fermenting soybean and wheat with a specific mold called Aspergillus oryzae to produce koji, which is then mixed with salt and water and left to ferment for several months. This allows for the development of its characteristic flavor and aroma. Additionally, shoyu is widely used in Japanese cuisine and has a balanced flavor profile that combines salty, sweet, umami, and occasionally slight bitterness.

The rising popularity of foreign food products has raised concerns about the halal status, as manufacture is not specifically for Muslim consumers. Non-halal soy sauce products may contain flavoring agents derived from brewery alcohol or pork. For example, some soy sauces undergo alcohol fermentation, which renders them non-halal if the alcohol is not completely removed. Japan produces one kiloliter of soy sauce annually, with exports to over 110 countries (Kataoka 2005). Recognizing the growing demand for halal products, Japan has started to take halal market seriously, as evidenced by the annual Japan Halal Expo, which showcases various halal products available in the country (Prabowo & Rahman 2016).

The limited knowledge of halal requirements among foreign food producers increases the risk of products containing questionable or non-halal ingredients (Marina 2003). As modern food processing technology advances, the complexity of ingredients used in food production grows, making it challenging for consumers to distinguish between halal and haram foods. Synthetic ingredients can also be halal if produced and verified according to halal standards. The global focus on food safety has led some non-Muslim consumers to prefer halal products, recognizing their superior safety, hygiene, and quality assurance (Riaz 2010). Therefore, the production of halal food products benefits both companies and Muslim consumers, given the rising demand for such products.

The objectives of this study are to (1) evaluate the conformity of shoyu production system with halal assurance system (HAS) 23000 criteria; (2) develop HAS for halal shoyu; (3) evaluate the conformity of the company's production system after development; and (4) identify related risks that may impact halal status of the company. The results are expected to guide soy sauce industry in producing halal soy sauce that complies with HAS 23000, enabling exports to Muslim-majority countries. This study aimed to contribute to the broader halal product industry by providing valuable insights into the role of halal certification in enhancing product quality, consumer trust, and market expansion.

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2 Literature Review

2.1 Halal Food

Food includes materials derived from biological sources and water, whether processed or unprocessed, and intended for human consumption. It also includes food additives, raw materials, and other substances used in the preparation and processing of food and drinks. According to the Islamic Sharia, the term "halal" literally refers to activities or products that are permitted and do not incur any penalty or reward (Kamali 2013).

Based on these definitions, halal food is permissible food for human consumption, particularly for Muslims. Meawhile, haram food refers to food that is prohibited for Muslims under Islamic Sharia. LPPOM MUI (2005) (Food, Drug and Cosmetic Research Institute of Indonesian Ulema Council) states that halal products must meet specific criteria under Islamic law. These criteria include a) No pork or ingredients derived from pigs. b) No brewery alcohol (khamr) or its derivatives, c) Any animal-derived ingredients must come from halal animals slaughtered according to Islamic methods; d) No prohibited or impure substances, such as carrion, blood, human organs, or feces; e) All storage, sales, processing, management, and transportation facilities must not be used for pigs or other non-halal items unless cleansed according to Islamic procedures.

Although halal food is more widely available than haram food, the incorporation of haram substances in food processing technology has caused an increase in its market availability. The Qur'an, in Surah Al-Maidah, verse 3, specifically identifies several types of forbidden foods for Muslims, including carrion, blood, pork, animals slaughtered in the name of deities other than Allah, strangled , beaten, fallen, or gored animals, and those sacrificed to idols, unless the animals are properly slaughtered according to Islamic law.

2.2 Halal Assurance System (HAS)

HAS is a crucial framework for ensuring that food products meet halal standards in the production processes. According to Rahman & Abdul (2017), it is designed to help companies monitor and control all aspects of halal production, preventing any non-compliance with halal requirements. This system is formally documented to reflect a company's commitment to producing halal products and ensuring that every step in the supply chain adheres to the regulations set by local halal authorities.

HAS was developed based on the principles of Total Quality Management (TQM) and emphasizes the role of every employee in maintaining product quality. TQM promotes a culture of continuous improvement and requires active participation from all employees, along with strong support from top management (Muhandri & Kadarisman 2005).

This system is similar to quality systems such as ISO and HACCP but specifically focuses on maintaining halal status of food products. It operates on three fundamental principles (Prabowo & Rahman 2016):

a. Zero Limit: No haram (forbidden) substances can enter the production process;
b. Zero Defect: Companies must avoid producing haram products, as this poses significant risks when discovered by consumers;
c. Zero Risk: By adhering to the first two principles, companies can mitigate risks related to their halal practices.

2.2.1 Practical Implementation of HAS

To effectively implement HAS, companies must establish clear procedures for obtaining ingredients, managing production, and verifying compliance at every step. This includes training employees on halal principles, ensuring thorough documentation processes, and maintaining communication with certification bodies. Companies also require contingency plans to address any non-compliance issues that arise.

2.2.2 Challenges in Implementing HAS

Implementing HAS can be challenging despite its importance. Common obstacles include:

a. Supplier Verification: Ensuring that all suppliers adhere to halal standards is complex, particularly in diverse supply chains. Companies must have robust tracking systems to verify halal status of all raw materials;
b. Limited Knowledge: Manufacturers particularly in non-Muslim-majority countries may lack a deep understanding of halal requirements. Educating all employees about halal compliance is essential for success;
c. Cost Concerns: Implementing HAS can be expensive, as it requires investments in training, system development, and regular audits. Smaller companies may struggle to allocate sufficient resources;
d. Regulatory Differences: International companies face challenges complying with varying halal standards across countries, complicating the compliance and certification processes;
e. Ongoing Monitoring: HAS requires continuous evaluation and adjustment to achieve compliance. Companies must stay updated on regulatory changes, ingredient sourcing, and production methods.

HAS implementation establishes a cyclical process that requires constant monitoring and periodic assessment to ensure effective halal production. This continuous evaluation is necessary to adapt to both internal and external changes. HAS cycle outlined by LPPOM MUI (2005) is shown in Figure 1.

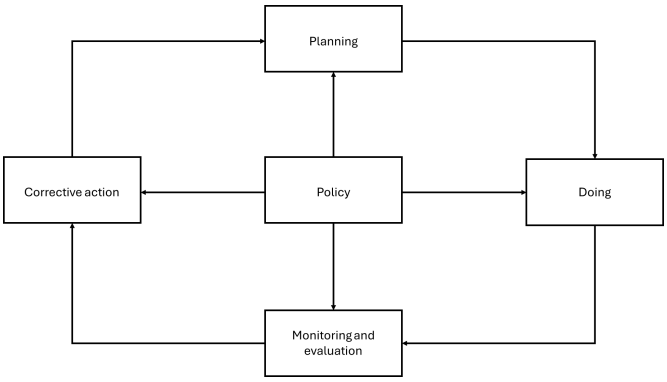

Figure 1: Halal assurance system cycle

2.3 Shoyu

Shoyu is a traditional Japanese soy sauce made from a mixture of soybean and wheat that undergoes a two-stage fermentation process. The first stage comprises cultivation of a koji mold starter, which produces protease and amylase enzymes. In Indonesia, this koji mold is commonly referred to as "bungkil" and the fermentation process typically lasts between 48 to 72 hours at temperatures below 40℃ (Lioe *et al.* 2010). The second stage involves adding brine with high sodium or salt concentrations, typically ranging from 17.5% to 20% w/v, to inactivate koji which is no longer required. This stage initiates fermentation aided by halophilic bacteria including Pediococcus halophilus and osmophilic yeast such as Saccharomyces rouxii. The fermentation period in modern industries ranges from 3 to 8 months, with the temperature dependent on ambient conditions. The product of this stage is known as moromi in Japan or baceman in Indonesia. Higher fermentation temperatures have been shown to accelerate the aging process of soy sauce, reduce ethanol content, and increase pH levels (Wu *et al.* 2010). The resulting moromi is then subjected to high-pressure pressing, producing a liquid extract called shoyu.

Aspergillus oryzae, Aspergillus sojae, and Aspergillus tamarii are common Koji used in the initial fermentation stage of soy sauce production across Japan, China, and Southeast Asia (Lioe *et al.* 2007). Shoyu possesses antimicrobial properties against various bacteria that cause food poisoning and has been found to exhibit anticarcinogenic, antioxidative, and antihypertensive effects. Additionally, it plays a role in stimulating human gastric acid secretion and contains several bioactive components, including amino acids, organic acids, and aromatic compounds (Murooka & Yamashita 2008).

3 Methodology

This study was conducted from January to March 2020 in shoyu manufacturing facility in Japan.

3.1 Observation

Field observations were conducted to directly examine shoyu production activities in Kamada Soy Sauce Inc., starting from procurement of raw materials, warehousing, production, product distribution to consumers, and the administration system used. The observation then continued with an evaluation of the company's HAS implementation.

3.2 Preliminary Adult

The company required a preliminary audit to assess its preparedness and condition for compliance with HAS criteria. Conditions that must be improved or developed were also evaluated. The audit was conducted according to the internal halal audit questionnaire checklist, with modifications made to convert it from qualitative to quantitative.

3.3 HAS Developmen

HAS development was carried out by improving the company's system to meet the requirements outlined by LPPOM MUI. The process was based on HAS 23000, with the gap analysis method used. A manual was then prepared after the process of developing HAS.

The development was done to fulfill the 11 criteria of HAS according to HAS 23000 guideline for food processing industries, which include: (a) Halal policy, (b) Halal management team, (c) Training and education, (d) Material; (e) Product, (f) Production facility, (g) Written procedures for critical activities, (h) Traceability, and (i) Non-conforming product handling.

3.4 Conformity Assessment

A conformity assessment was conducted by comparing the results of the preliminary and post-audits. The post-audit is essential for evaluating the company's compliance with the 11 halal criteria. This audit was carried out using the internal halal audit questionnaire similar to the preliminary audit.

3.5 Risk Analysis

Risk analysis was performed using Failure Mode and Effects Analysis (FMEA) method. This approach is effective in identifying potential product or process issues before a non-conformity occurs (McDermott *et al.* 2009). FMEA method quantifies the potential risk of failure in a process. In this study, FMEA measured the potential risk of non-compliance with HAS 23000. The potential risk was determined by multiplying the severity of the impact, the probability of occurrence, and the level of detectability.

FMEA process included these stages: (1) Brainstorming with stakeholders in the company to identify risks associated with HAS; (2) Collaborative assessment with stakeholders to establish severity and detectability parameters, referencing relevant literature (Table 1); (3) Determination of occurrence parameters based on the percentage of compliance with each of the 11 principles of HAS 23000, as derived from the post-audit results (Table 2), (4) Calculation of Risk Probability Number (RPN) using Equation (1); and (5) Constructing a fishbone diagram based on identified risks. Risks with a high RPN score show likely major risks that need to be prioritized.

$$RPN = \mathrm{S} \times \mathrm{O} \times \mathrm{D} \quad \text{..... (1)}$$

where:

RPN : Risk probability Nnmber,

S : Severity parameter score,

O : Occurrence parameter score,

D : Detectability parameter score,

Table 1: Scoring criteria for severity and detectability parameters of failure mode and effects analysis risk analysis

Score	Severity	Detectability
1	Risk does not affect the product's halal status	Non-conformities are easily detected by all employees
2	Risk has a small possibility of affecting the product's halal status	Non-conformities can be detected by related personnel
3	Risk has a probability of affecting the product's halal status	Non-conformities can be detected by halal management team
4	Risk has a high probability of affecting the product's halal status	Non-conformities are hard to detect and have a possibility of bias
5	Risk directly affects the product's halal status	Non-conformities are very hard to detect and have a high chance of bias

Table 2: Scoring criteria for occurrence parameter of failure mode and effects analysis risk analysis

Score	Occurrence	Percent conformity (%)
1	All requirements met and implementation of halal assurance principles assured	100
2	Minor non-conformities present, but do not significantly affect halal status of the product	80-99
3	Requirements fulfilled partially and implementation of halal assurance principles not quite assured	60-79
4	Requirements not fulfilled but understood, implementation of halal assurance principles not assured	40-59
5	Requirements not fulfilled nor understood, implementation of halal assurance principles not assured	0-39

4 Result

4.1 Preliminary Audit

Preliminary audit was conducted during the last week of January 2020 to assess the initial condition of shoyu manufacturing facility in terms of HAS. Audit used a checklist based on halal internal audit questionnaire developed for this purpose. A gap analysis was performed to identify any non-conformities present, as shown in Table 3. It was observed that all 11 halal criteria exhibited non-conformities. This shows the importance of developing a robust HAS in the company. Although the company has several components required for ISO 9001, such as a quality policy, quality management team, training schedule, written procedures, non-conformity handling procedure, an internal audit procedure, and management review procedures, these documents do not include halal-related instructions. Consequently, a separate halal assurance manual was developed to ensure compliance with HAS 23000.

The quantitative results of preliminary audit are shown in Table 4. Scoring was conducted using a 3-point scale, where 0 implied no conformity and 3 showed complete conformity. Halal criteria 1, 2, 3, and 10—pertaining to halal policy, halal management team, training and education, and halal internal audit—received a conformity score of 0.00%, showing no compliance. However, halal criteria 7, 8, 9, and 11—related to written procedures for critical activities, traceability, non-conformity handling, and management review—achieved conformity rates above 50%, with scores of 64.33%, 66.67%, 100.00%, and 93.33%, respectively. The remaining halal criteria scored below 50.00%.

4.2 Conformity assessment

The conformity assessment was conducted in two phases. The first phase comprised an audit to evaluate the company's condition following HAS development. The results of the post-audit are summarized in Table 5. According to the results, 6 of 11 halal criteria, namely product, production facility, traceability, non-conform product handling, internal audit, and management review, fully conformed to the requirements of HAS 23000, achieving a conformity rate of 100.0%. The remaining criteria scored above 80.0%, except for material criteria, which recorded a conformity rate of only 55.67%. This lower score is primarily attributed to the non-compliance of Sugar A with the standards set by HAS 23000. Following audit, a comparison was made between the results of preliminary audit conducted before development and the post-audit conducted after the implementation of HAS. The differences in conformity percentages between these two assessments are shown in Table 6.

The differences in conformity rates before and after HAS development were quite significant. As shown in Table 6, the conformity rates for 10 criteria of HAS 23000 increased, with improvements ranging from 6.7% to 100.0%. The most significant improvement was observed in the internal audit criteria, which experienced a 100% increase in conformity. Meanwhile, the non-conforming product handling criteria did not show an increase in conformity rate, as it had already fully conformed to HAS 23000 from the outset.

4.3 Risk Analysis

Using RPN score of all identified risks, a control chart was constructed. According to Sholichah *et al.* (2017), Upper Control Limit (UCL) and Lower Control Limit (LCL) for the control chart were set at 1.5 and 0.5 times the average RPN score, respectively. Risks that exceed UCL are considered out of range, necessitating the implementation of corrective actions (Table 7).

Figure 2 shows FMEA control chart, It with three identified risks—R4, R6, and R7—exceeding the upper control limit. This signals a need for corrective actions by the company to address these out-of-control risks. For risk R4, which pertains to the knowledge of halal management team, team members should engage in regular training sessions led by halal management team leader. These meetings will enhance the team's understanding and adherence to HAS. Concerning risks R6 and R7, it is advised that the purchasing department notify halal management team of any new materials procured. This proactive communication allows for timely assessments of the new materials' conformity with HAS 23000, ensuring that all ingredients used are compliant with halal standards.

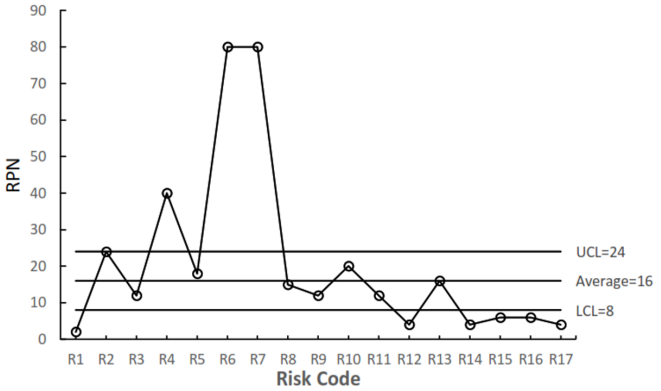

Figure 2: Failure mode and effect analysis control chart of identified risks; upper control limit (UCL), lower control limit (LCL)

Table 3: Result of gap analysis based on preliminary audit

Criteria	Available system	Gap	Follow-up
Halal policy	Quality policy available	Present	Add halal policy inside company's quality policy
Halal management team	Quality management team available (specifically assigned for HACCP (hazard analysis and critical control point) and ISO (international organization for standardization))	Present	Appointment of halal management team or adding job desk for existing quality management team
Training and education	Standard operating procedures for training is available but does not contain halal aspects	Present	Develop training material and conduct internal training
Material	Material list available but not yet checked regarding its conformity with halal assurance principles	Present	Evaluate material conformity with halal criteria. If nonconformities present, technology department must advise alternatives
Product	Alcoholic taste and aroma present	Present	Revise formula according to halal criteria
Production facility	Production line used concurrently with products containing brewery alcohol	Present	Alternatives: (a) Invest in a new dedicated line for halal product, (b) Ensure no pork materials present in the same line, (c) Clean alcohol before production
Written procedures for critical activities	ISO 9001 Standard operating procedures for critical activities available, but do not contain halal aspects	Present	Revise procedures by adding halal aspects inside procedures for critical activities
Traceability	Traceability system can trace until the raw material producer and production line and date	Present	Several materials in the existing product cannot be traced regarding halal status
Non-conform product handling	Standard operating procedures for product recall and disposal are available, but do not contain halal aspects	Present	Revise handling procedures by modifying the definition of non-conform products according to HAS (halal assurance system) 23000
Internal audit	ISO 9001 internal audit schedule and standard operating procedures are available, but do not contain halal aspects	Present	Revise procedure by adding halal aspect, including schedule and checklist
Management review	Schedule and standard operating procedures for ISO 9001 management are available, but do not contain halal aspects	Present	Revise procedure by adding halal aspect

Table 4: Preliminary audit result regarding 11 halal criteria of halal assurance system 23000

Criteria	Audit results	
	Mean score (3-point scale)	Percent of conformity
Halal policy	0.00	0.00
Halal management team	0.00	0.00
Training and education	0.00	0.00
Material	0.67	22.33
Product	1.50	50.00
Production facility	1.00	33.33
Written procedures for critical activities		
a. New material selection	1.50	50.00
b. Purchasing	1.50	50.00
c. New product development	1.50	50.00
d. Material inspection	2.67	89.00
e. Production	2.00	66.67
f. Cleaning	1.80	60.00
g. Storage	1.50	50.00
h. Transportation	3.00	100.00
Average	1.93	46.33
Traceability	2.00	66.67
Non-conform product handling	3.00	100.00
Internal audit	0.00	0.00
Management review	2.80	93.33

Table 5: Post audit result regarding 11 halal criteria

Criteria	Audit results	
	Mean score (3-point scale)	Percent of conformity
Halal policy	2.50	83.3
Halal management team	2.60	86.7
Training and education	2.86	95.8
Material	1.67	55.7
Product	3.00	100.0
Production facility	3.00	100.0
Written procedures for critical activities		
a. New material selection	3.00	100.0
b. Purchasing	2.50	83.3
c. New product development	3.00	100.0
d. Material inspection	2.67	89.0
e. Production	2.67	89.0
f. Cleaning	3.00	100.0
g. Storage	3.00	100.0
h. Transportation	3.00	100.0
Average	2.85	95.0
Traceability	3.00	100.0
Non-conform product handling	3.00	100.0
Internal audit	3.00	100.0
Management review	3.00	100.0

5 Discussion

5.1 HAS Development

HAS, which was based on HAS 23000, comprised 11 criteria. The development and changes made to each criterion are detailed below.

5.1.1 Halal Policy

Halal policy is a written commitment by the company to produce halal products. Shoyu manufacturing policy states that "The manufacturer is committed to producing halal products that meet the needs of all consumers, including Muslims." This policy serves as the foundation for developing and implementing HAS. To ensure stakeholder understanding, halal management team conducted verbal briefings on the company's halal production and marketing strategies.

5.1.2 Halal Management Team

Halal management team is responsible for implementing, evaluating, and continuously improving HAS. This team supervises halal product manufacturing process and is led by a coordinator who oversees team members representing the five company departments.

Table 6: Post audit result regarding 11 halal criteria

Criteria	Percent of conformity		
	Pre-audit	Post audit	Difference
Halal policy	0.0	83.3	+83.3
Halal management team	0.0	86.7	+86.7
Training and education	0.0	95.8	+95.8
Material	22.3	55.7	+33.3
Product	50.0	100.0	+50.0
Production facility	33.3	100.0	+46.7
Written procedures for critical activities			
a. New material selection	50.0	100.0	+50.0
b. Purchasing	50.0	83.3	+33.3
c. New product development	500	100.0	+50.0
d. Material inspection	89,0	89.0	+0.0
e. Production	66.7	89.0	+22.3
f. Cleaning	60.0	100.0	+40.0
g. Storage	50.0	100.0	+50.0
h. Transportation	100.0	100.0	+0.0
Average	64.3	95.0	+30.7
Traceability	66.7	100.0	+23.3
Non-conform product handling	100.0	100.0	+0.0
Internal audit	0.0	100.0	+100.0
Management review	93.3	100.0	+6.7

5.1.3 Training and Education

Training aims to enhance the knowledge, skills, and behaviors of employees, particularly those involved in critical activities. Both internal and external training are required to meet HAS 23000 standards. Internal training, conducted by halal management team and the author on March 17, 2020, focused on the importance and implementation of HAS. This training is mandated annually and documentation of includes attendance lists and post-test results. Additionally, external training, provided by LPPOM MUI and Indonesian Halal Training and Education Center (IHATEC), must be attended by a minimum of one employee, preferably a member of halal management team.

5.1.4 Material

According to LPPOM MUI (2012), materials include substances used directly or indirectly in processing. They are categorized as raw materials, food additives, and processing aids. Raw materials and food additives are integral to the final product, while processing aids assist in production without being part of the final product. HAS 23000 states that all materials must be halal, and their origins must be traceable.

Supporting documents are necessary to verify halal status of materials. These documents may include halal certificates from MUI or other recognized bodies, technical specifications, production flowcharts, and statements of pork-free facilities. Materials listed positively are inherently halal without critical processes affecting their status and do not require supporting documents. Table 5 shows the material list for Shoyu production, categorized into raw materials, food additives, and processing aids. High-risk materials, particularly those from animal derivatives, require halal certificates, while non-high-risk materials need other supporting documentation, as detailed in Table 8 and Table 9.

Shoyu production initially included brewery alcohol and mirin, which are not permissible for Muslims. To achieve halal certification, these ingredients must be excluded. Flavor enhancers are complex and high-risk, and require halal certification to confirm halal status. Flavor enhancers lacking halal certificates were excluded from halal formulation.

5.1.5 Product

Shoyu producers have planned to launch a new halal product aimed at Muslim consumers. The existing shoyu contained brewery alcohol, specifically mirin, which served as a flavoring and preservative agent. However, this ingredient did not comply with HAS 23000 due to its sensory profile of taste and aroma. Following further development by the technology department, the company successfully developed a new product that eliminated the use of alcohol and pork-derived materials. All ingredients now have supporting documentation to validate halal status. The new material meets the sensory criteria of HAS 23000, making it suitable for halal certification. Moreover, the implementation of the ISO 9001 and HACCP quality management systems ensures the safety of the production chain through to distribution, thereby preventing any external contamination that could compromise halal status of the product.

5.1.6 Production Facility

Facilities consist of all production lines and equipment used in product manufacturing. The production line was initially dedicated to soy sauce production in retort packaging, however, with the closure of that business unit, the available space and equipment can now be used for halal production.

Table 7: Failure mode and effect analysis of identified risks

Code	HAS criteria	Identified risks	S	O	D	RPN	Rank
R1	Halal policy	Halal policy does not meet HAS 23000 requirements	1	2	1	2	11
R2	Halal management team	Team members not appointed	3	2	4	24	3
R3	Halal management team	At least one member did not attend external training	2	2	3	12	7
R4	Halal management team	Team knowledge regarding halal and haram materials is inadequate	4	2	5	40	2
R5	Training and education	Internal training and education regarding HAS 23000 is inadequate	3	2	3	18	5
R6	Materials	Materials cannot be verified regarding their halal status	5	4	4	80	1
R7	Materials	Materials do not have supporting document of their halal status	5	4	4	80	1
R8	Product	Product name and profile does not conform to Islamic sharia	5	1	3	15	7
R9	Production facilities	Material storage contaminated with najis/haram materials	4	1	3	12	8
R10	Production facilities	Production line is contaminated with najis/haram materials	5	1	4	20	4
R11	Production facilities	Finished goods storage contaminated with najis/haram materials	4	1	3	12	8
R12	Production facilities	Finished goods transport contaminated with najis/haram materials	2	1	2	4	10
R13	Written procedures for critical activities	Written procedures not concise and not capable of ensuring HAS	2	2	4	16	6
R14	Traceability	Traceability system unable to trace materials used in production	2	1	2	4	10
R15	Non-conform product handling	Halal products that inadvertently became non-halal products due to contamination that were sold to the market were not recalled	2	1	3	6	9
R16	Internal audit	Internal audit does not meet HAS 23000 requirements/not done	2	1	3	6	9
R17	Management review	Management review does not cover HAS	1	1	4	4	10

Note: HAS =Halal Assurance System; S=Severity; O=Occurrence; D=Detectability; RPN=Risk Probability Number

The production process started with the receipt of raw soy sauce from the supplier, referred to as kiage. This raw soy sauce was stored in kiage room, where it was heated and allowed to sit to facilitate the precipitation of solid materials. Subsequently, Kiage was filtered using a filter and filter paper, with diatomaceous earth powder added to trap any remaining

micro-proteins. A quality control check was performed at this stage to test turbidity, and if kiage passed the check, it proceeds to the next step.

The validated kiage was then transferred to a moving tank, transporting it from kiage room to the mixing room located in the retort production line of the adjacent building. In the mixing room, kiage was combined with a dashi extract solution, made by heating water infused with dried fish and kelp, followed by filtering. The mixing process occurred in a dedicated mixing tank, and subsequently, another quality control check was conducted by the quality control department to assess pH, water activity, color, and salinity.

The mixed soy sauce solution was transferred to paper pack filling machine number 3. This machine had a lower productivity rate than other filling machines, which is why it was specifically designated for this purpose. Prior to filling, soy sauce mixture was heated in a pasteurizer. After undergoing Sharia cleaning, product filling into the paper carton packaging was carried out in the designated machine. On completion, an automatic weight check was performed, followed by a cooling process that included water spraying and air-blowing to remove residual moisture. The production code and expiry date were then laser-printed on the packaging. The finished sauce was stored in a warehouse on a separate pallet, ensuring that the production process effectively prevented cross-contamination from non-halal materials.

Table 8: Materials and ingredients checklist

Ingredients	Halal traceability	Existing product	Halal product
Processing Aids			
Bleaching earth	Halal positive list	O	O
Silicon oxide	Halal positive list	O	O
Raw Material			
Water	Halal positive list	O	O
Dried bonito	Halal status traceable	O	O
Dried mackerel	Halal status traceable	O	O
Kelp	Halal positive list	O	O
Raw soy sauce	Halal status traceable	O	O
Sugar	Halal status traceable	O	O
Salt	Halal status traceable	O	O
Maltodextrin	Halal status traceable	O	X
Alcohol	Not-acceptable	O	X
Mirin	Not-acceptable	O	X
Flavor enhancers	Halal assurance system halal certificate	O	O

Note: O=Used in formulation; X=Not used in formulation

Table 9: Material supporting document requirements of Halal Dashi soy sauce

Ingredients	Risk	Required documents	Remarks
Water	No risk	-	Pass, included in halal possitive list
Dried bonito	low risk	process flowchart	Pass
Dried mackerel	low risk	process flowchart	Pass
Kelp	low risk	process flowchart	Pass
Bleaching earth	low risk	Process flowchart, technical specification	Pass, all chemical materials
Silicon oxide	No risk	-	Pass, included in halal possitive list
Raw soy sauce	low risk	Process flowchart, technical specification, statement of pork-free facility	Further supporting documents regarding bacteria, mold, and yeast used are needed
Sugar	low risk	Process flowchart, technical specification	Further supporting documents needed (possibility of nonhalal bovine bone char present)
Salt	low risk	Flowchart, technical specification	Pass
Flavor enhancer	High risk	Halal certificate	Pass, halal assurance system halal certificate
Acidity regulator	Low risk	Process flowchart, technical specification	Pass, all chemical materials

5.1.7 Written Procedures for Critical Activities

Written procedures for critical activities consisted of a set of operational protocols designed to control and prevent non-conformity in key activities. According to LPPOM MUI (2012), critical activities include activities in the production chain that could potentially impact a product's halal status. Kamada Soy Sauce Inc. developed written procedures as part of their ISO 9001 quality management system, addressing critical activities such as material selection, purchasing, new product development, material receiving, production, sanitation of facilities and equipment, storage of materials and finished goods, and transportation. All critical activities must adhere to the outlined procedures in HAS manual, under the supervision of halal management team. The complete list of procedures for critical activities is shown in Table 10.

5.1.8 Traceability

Traceability refers to a system capable of tracking and providing relevant information about a product in the entire distribution chain. This system must offer insights into the materials used and the effects of both the production and distribution processes on food quality and safety. Shoyu producers implemented a tracing system that verifies compliance with HAS 23000 criteria. Each product produced by the company features a production code imprinted on the front of the packaging, allowing for the tracking of materials, production lines, and the names of responsible personnel or operators. By referencing the production date and factory location, the company can efficiently trace back and gather all necessary information regarding the production process.

Table 10: List of written procedures for halal critical activities

Department	Activity	Document no.
Purchasing	SOP of supporting document for material	R-84-1-001
Purchasing	SOP for new material selection	R-84-1-001
Purchasing	SOP for material purchasing	R-84-1-001
Technology	SOP for new product development	R-83-1
Purchasing	SOP for material receiving	R-84-1
Technology	SOP for material sampling	R-85-4
Production	SOP for production	M-85-2
Production	SOP for sanitation and cleaning	M-85-1
Production	SOP for material storage	M-85-1
Production	SOP for finished goods storage	M-85-1
Production	SOP for transportation	R-82-1-008

SOP (Operational standard)

5.1.9 Non-Conform Product Handling

According to LPPOM MUI (2012), a product is considered non-conforming if it is damaged, rotten, or has been certified halal despite being produced with materials or facilities that do not meet LPPOM MUI standards. Products that closely resemble non-halal products in sensory profile, aroma, and taste are also classified non-conforming and must be disposed of appropriately.

To prevent potential cross-contamination, the manufacturer commits to discarding products that do not comply with quality standards and HAS 23000 criteria. A product recall is initiated when multiple customer complaints arise from already distributed products. A complaint is considered valid if a minimum of two customers report the same problem from a particular production lot in a specified timeframe.

The procedure begins when a customer submits a claim to the factory. The manager carries out a process known as product tracing and reviews the relevant production line documentation. If any discrepancies are discovered with the materials, the company will instruct the distributor to contact the manufacturer for additional information or clarification. If ingredient-related issues are confirmed, the manufacturer will relay this information through the distributor to the quality assurance department at the factory. The company can then identify the customers who received the affected product, initiate a recall of the defective items, and replace them with new ones. This subsequent process is referred to as product tracking.

5.1.10 Internal Audit

The representatives of halal management team conducted the internal audit to evaluate the conformity of HAS implementation in the company with the criteria outlined in HAS 23000. The scope of the internal audit encompasses all aspects of HAS 23000 criteria. Two internal audits were performed: a preliminary audit prior to HAS development and a post-audit following its implementation.

5.1.11 Management Review

Management review is essential for fostering continuous improvement through a comprehensive assessment of the continuity, conformity, and adequacy of HAS system. This review must be conducted a minimum of once a year and should include all relevant stakeholders, including top management. Discussion points for management review may arise from internal audits, external audits, or previous management reviews. Kamada Soy Sauce Inc. conducts its management review annually, in compliance with the requirements of ISO quality management system. Management review for HAS 23000 will be conducted concurrently with this annual schedule.

5.2 Risk Analysis

FMEA method was used by Kamada Soy Sauce Inc. to conduct risk analysis on HAS. Several risks were initially identified and compiled based on the previous audit results. A total of 17 risks were identified, including all 11 criteria of HAS 23000. For each risk, scores were assigned across three categories, including severity, occurrence, and detectability. These

scores were determined through brainstorming and discussion sessions with relevant stakeholders in the company, alongside insights from the post-audit results.

RPN was determined by multiplying the scores from the three categories. A high RPN showed a greater likelihood of a risk occurring, warranting priority over other risks with lower RPN. In terms of severity, risks associated with materials, products, and the production line received the highest score of 5, as they directly impacted halal status of the product. Non-conformities in these areas caused the product to be classified as non-halal. If the materials used were non-halal or if the sensory profile of the product resembled haram products, the product would be deemed haram. Additionally, contamination of haram materials in the production line would also compromise halal status of the final product.

Regarding occurrence, non-conformities related to material criteria were found to be the most frequent, with an occurrence score of 4. This was primarily due to insufficient supporting documents to verify halal status of the materials. However, other criteria were less frequently non-conforming and scored between 1 and 2.

Detectability scores were highest for halal management team, specifically concerning their knowledge of HAS, with a score of 5. In Kamada Soy Sauce Inc., halal management team played a crucial role, particularly because the majority of employees were not Muslim. Therefore, they were the only personnel with comprehensive knowledge of HAS 23000.

According to Table 10, the highest RPN was assigned to risks R6 and R7, with RPN score of 80, associated with material criteria. These risks had a significant impact on halal status of the product, were relatively difficult to detect, and frequently occurred during audit. Risk R4, concerning the knowledge of halal management team, received the second highest RPN of 40, while risk R2, related to the appointment of halal management team, ranked third with an RPN of 24. Risks associated with halal policy, traceability, non-conform product handling, internal audit, and management review generally posed lower risks, reflected by their low RPN scores. Additionally, 11 different RPN scores were generated for all 17 identified risks, with R6 and R7 showing the highest scores, while R1, associated with halal policy, received the lowest.

Based on the identified risks and their corresponding RPN numbers, a fishbone diagram was constructed. The primary problem addressed in the diagram was that the product was not halal certified due to deviations in the 11 criteria of HAS 23000. Fishbone diagram was based on the 4M concept, which categorized potential causes into four groups. These groups include man, machine, method, and material. The closer a risk is to the root problem, the higher its RPN score. Risks R6, R7, and R8 were associated with the materials used in production, and R6 and R7 had the highest RPN score of 80. R2, R3, R4, and R5 were related to manpower, with R4 having the highest RPN score of 40. R9, R10, R11, and R12 pertain to machinery, and R10 had the highest RPN score of 20. R1, R13, R14, R15, R16, and R17 are associated with methods, with R13 having the highest RPN score of 16. Fishbone diagram is shown in Figure 3.

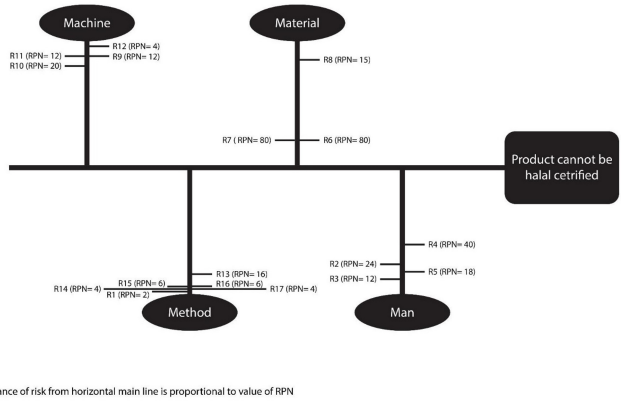

Figure 3: Fishbone diagram regarding halal assurance system in Shoyu manufacture, risk probability number (RPN)

6 Conclusion

In conclusion, HAS implementation at the company led to a significant increase in conformity rates based on HAS 23000. The area with the lowest conformity was related to materials, as one of the raw ingredients failed to meet halal product requirements. A brainstorming session resulted in the identification of 17 risks, covering all 11 criteria of HAS 23000. These risks were assessed using FMEA method, and three of them (R4, R6, and R7) required corrective measures. A fishbone diagram was created to organize the risks into four primary categories, including material, man, machine, and method, with the material category being the most closely related to the issues identified.

This study showed a substantial improvement in compliance with HAS 23000 at Kamada Soy Sauce Inc. following the introduction of HAS, with the average compliance rate increasing from 64.33% to 95.00%. Although the material category exhibited the lowest compliance, the identification of seventeen risks allowed for targeted corrective action.

These results have significant implications for soy sauce producers and the wider food industry. By implementing a robust HAS, businesses can build consumer trust and explore new market opportunities in halal sector, aiding compliance and enhancing competitiveness. However, the focus on a single company may limit the generalizability of the results to other organizations. Future study should explore the effectiveness of HAS across various contexts and industries. To obtain halal certification, companies should carry out thorough audits, develop comprehensive assurance systems, provide ongoing employee training, and continuously evaluate risks to ensure adherence to halal standards.

Conflict of Interest

The authors declare no conflict of interest.

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