IMPLEMENTATION OF HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) IN THE MEDIUM SCALE OF TOMATO SAUCE FACTORY : A CASE STUDY.

(PENERAPAN HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) DI PABRIK SAUS TOMAT SKALA MENENGAH: STUDI KASUS)

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ABSTRACT

Implementation of hazard analysis critical control point (HACCP) in the medium scale food industry had been studied by choosing a case of tomato sauce factory. The objective was to study the readiness of medium scale food industry in Indonesia in implementing the HACCP. The model that was designed for the tomato sauce factory can be used as a guide by similar food factory (factory of acid food products, pH 3.6 – 4.5, using pasteurization technology for preservation).

The analysis was conducted using descriptive method through four modules, i.e.: I. assessment on the existing prerequisite programs and management on food safety system; II. identification of potential critical points; III. developing a program of HACCP system; IV. implementation of the system and evaluation of the results. The results showed that the existing conditions of the tomato sauce factory that was chosen as a case has not comply to the requirement, neither in the prerequisite programs nor in the management on food safety system. Five potential hazards were identified along the process to be controlled as CCP's. The designed system of HACCP program covered the improvement of the prerequisite programs and Sanitation Standard Operating Procedures (SSOPs), employee training and education, and investment in equipments to enhance their ability to operate the system. Total cost for implementing the system was around Rp 180 millions, while the time needed since designing up to fully operating the system with audit results fulfill the prerequisite programs and HACCP requirement was about 12 months.

It was concluded that to fulfill the requirement of food safety management and HACCP system the medium scale food industry in Indonesia still needs to improve its basic condition. More intensive socialization to food processors for their better understanding on food safety and HACCP is urgently needed.

Keywords : HACCP, tomato sauce, food safety, case study.

ABSTRAK

Penerapan sistem hazard analysis critical control point (HACCP) di industri makanan skala menengah dikaji dengan mengambil pabrik saus tomat sebagai studi kasus. Kajian bertujuan untuk mempelajari kesiapan industri skala menengah di Indonesia dalam menerapkan HACCP. Berdasarkan hasil kajian, dirancang model penerapan HACCP yang diharapkan dapat digunakan sebagai panduan untuk pabrik sejenis lainnya (pabrik produk pangan berasam, pH 3,6–4,5, diawet dengan teknologi pasteurisasi).

Analisis dilakukan menggunakan metode deskriptif melalui empat modul, yaitu: I. mengkaji kondisi pabrik saus tomat sebelum menerapkan sistem HACCP; II. mengidentifikasi potensi titik kritis sepanjang alur proses; III. menyusun program implementasi HACCP; dan IV. mengevaluasi program penerapannya. Hasil kajian menunjukkan bahwa kondisi pabrik saus tomat studi kasus belum memenuhi persyaratan dasar untuk mengimplementansikan HACCP, begitu pula pengelolaan sistem keamanan pangan yang diterapkannya. Teridentifikasi lima potensi titik kritis yang perlu dikendalikan secara efektif sebagai CCP's. Program implementasi HACCP yang dirancang mencakup perbaikan dari persyaratan dasar termasuk pembuatan SSOP-nya, pendidikan dan pelatihan karyawan, dan investasi peralatan untuk mendukung beroperasinya sistem HACCP. Hasil evaluasi menunjukkan bahwa biaya penerapan HACCP mencapai sekitar 180 juta rupiah dan waktu yang diperlukan sejak merancang dan mengoperasikan sistem sampai hasil auditnya memenuhi persyaratan dasar dan sistem HACCP mencapai sekitar 12 bulan.

Dari kajian ini disimpulkan bahwa kecukupan pengelolaan sistem keamanan pangan dan penerapan HACCP di industri skala menengah masih memerlukan upaya yang bersifat mendasar untuk memperbaiki kondisi perusahaan. Diperlukan upaya sosialisasi yang lebih intensif untuk meningkatkan pengetahuan dan kesadaran para pelaku industri dalam masalah keamanan pangan dan HACCP.

Kata kunci: *HACCP, saus tomat, keamanan pangan, studi kasus.*

INTRODUCTION

The consumers continuous demands for higher quality and safety of food products enhanced the requirements prescribe by the standards for the food industry. This development combined with tight competition between the food companies have resulted in placing the assurance of safe production and the supply of adequately safe and healthy food products as the main aims of the food industry. These aims can be attained by adopting a systematic and organizational structure, controlling activities, procedures and resources according to the standards which constitute the basis for the total quality system (TQS), including the ISO 9000 series (Early, 1995).

ISO 9000 is applicable to any industry irrespectively of the kind production or service. Meanwhile since food is more sensitive due to directly consume by human, the implementation of TQS in the food industry is exclusively guided by the Hazard Analysis of Critical Control Point (HACCP). HACCP system is a process which identifies and assesses the hazards and risks associated with the manufacture, storage, and distribution of foods and implement the appropriate controls aiming at the elimination or reduction of these hazards at specific points of production line (Moy et al, 1994). HACCP has become the internationally accepted approach for assuring the safety of food.

To assure consumer health protection and fair practices in trade Indonesia governments issued an Indonesian Food Act number 7 in 1996 stated that every food industry, regardless its scale, must implement a good sanitation and safety process. Based on this act, the Codex text Guidelines for the application of the HACCP system (Codex Alimentarius Commission/CAC, 1993) was adopted as Indonesian National Standard (SNI) 01-4852-1998 and National Standardization Agency (BSN) Directive 1004-1999. Ministry of Industry will soon issued a decree to declare the Good Manufacturing Practices (GMP) as compulsory for food industry.

This study was aimed to learn the readiness of food industry in Indonesia in implementing the HACCP. Since food industry covered a very large variety of products, a case study was decided to conduct. Based on the fact that large scale industries generally have capability of implementing the system, the study was focused to the medium scale. Tomato sauce was chosen due to its fast growth of production, i.e. 6 % per annum in

NACMCF, 1998), by examining the characteristic of the raw materials, ingredients and finished products, and evaluating the variables that could influence the safety of tomato sauce product. The CCP determination were identified through application of five question steps Decision Approach (Bryan, 1992; CAC, 1997; Mortimore and Wallace, 1994) to reach steps of the tomato sauce formula preparation and production.

Module III: Program of HACCP was developed through a workshop/training and its implementation was assisted and evaluated regularly.

To assist the factory's operators and management in implementing HACCP principles, a four day HACCP training/ workshop was planned and organized. The objectives of this training was: (a) to impart a common understanding of the practical implications of HACCP to food safety on worldwide bases, (b) to impart the practical skills and knowledge necessary for HACCP application, and (c) to provide the stimulus for further development and harmonization of HACCP. The substance of the training was GMP and sanitation standard operating procedures (SSOP), and seven principles of HACCP. Participants were asked to apply these principles in developing a HACCP plans for a formula preparation model process. Potential preventive measures and process controls were reviewed and processor was urged to develop GMP, SSOP and HACCP plans specific to their operation. Discussions on major problems in the tomato sauce formula production and suggestion for improvement were prompted.

The HACCP system was designed. Risk analysis and HACCP principles as outlined by CAC (1997) and National Advisory of Committee on Microbiological Criteria for Foods/ NACMCF (1998) were used as the basis for safety initiative.

To start implementing the HCCP program a team that focuses on the implementation were established. Team members were selected based on their professional background, experience and degree of involvement in the production process; e.g. tomato sauce plant manager, quality control manager, production manager, production supervisor, head of laboratory, food production specialist with HACCP implementation experience.

Before the prerequisite HACCP work was initiated, a series of meetings were organized to discuss the basic principles and steps of HACCP plan development, the function and responsibility of every professional in the team, and the schedule to complete the process. The most suitable starting point, type of information/documents needs to develop, and the cost of implementing the system was also decided.

Module IV: Evaluation of HACCP Programs were focused on costs of HACCP implementation, time schedule, and auditing

Costs of HACCP implementation and time needed to fully implement the system were analyzed through deep interviewing the operators, middle and top ranks of the management. The interview was done to discover the seriousness of every single person in the industry in implementing the HACCP system. HACCP programs would not be operated automatically.

Quality and Safety Audit were aimed to asses the quality and safety system to ensure that procedures written in the manual were being followed and effective in practice. The quality and safety audit was assisted by the Australian *Institute of Environmental Health* (AIEH). The method used for collecting objective evidence was by means of interview, observation of work place activities and/or environmental conditions and verification of the HACCP plan especially the temperature and retention time of pasteurization. The scope of the audit included: sourcing of raw materials, transport of raw material to manufacturing facility, incoming material, production, post production, employee, documentation and facility uses a HACCP system and the ability to demonstrate the planned system was used routinely.

RESULT AND DISCUSSION

Existing Conditions

The assessment result of the GMP, food safety management system and food hygiene practices implemented in the case study tomato sauce factory was shown in Table 1 and Table 2.

Table 1. Condition of prerequisite programs.

No.	Prerequisite	Remarks/Condition		
		Poor	Fair	Good
1.	Premises and facilities	-	-	V
2.	Receiving, storage and transportation	V	-	-
3.	Equipments	-	V	-
4.	Cleaning and Sanitation	-	V	-
5.	Housekeeping and Pest control	V	-	-
6.	Personnel hygiene and Health requirements	V	-	-
7.	Manufacturing control and Documentation	V	-	-
8.	Recall and Withdraw	-	V	-

Table 2. Food safety management systems and food hygiene practices.

No.	Food safety management & food hygiene practices	Remarks Condition		
		Poor	Fair	Good
1.	Aspect of staff training	V	-	-
2.	Monitoring of staff for personnel hygiene and illness/ infections	V	-	-
3.	Cleaning and sanitation schedules	-	V	-
4.	Food handling and storage programs	V	-	-
5.	Stock rotation	-	-	V
6.	HACCP Training	V	-	-
7.	Full HACCP implementation system	V	-	-
8.	Temperature monitoring of foods	V	-	-
9.	Inspection of foodstuffs on delivery	-	V	-
10.	Microbiological testing	-	V	-
11.	Documentation of food hygiene practices	V	-	-

Table 1 and Table 2 shows that the implementation of GMP as prerequisite programs on HACCP and food safety management system practiced by the tomato sauce factory had not sufficient yet. Therefore, all of the prerequisite programs should be revised to assure that each segment of the factory provide the necessary condition to protect food while it is under their control.

The implementation of GMP plays an important role in controlling potential health hazards. Unfortunately the case of tomato sauce factory was practiced a more likely poor GMP, reflected by poor remarks on aspects of receiving, storage and transportation; housekeeping and pest control; personnel hygiene and health requirements; manufacturing control and documentation. Table 2 was also shown that the case study factory was not sufficiently practiced the food safety management and basic food hygiene, reflected by poor condition aspects of staff training, monitoring of staff for personnel hygiene and illness/infections, food handling and storage programs, HACCP training, temperature monitoring of foods, and documentation of food hygiene practices.

The poor remarks on GMP implementation could be resulted by some factors, i.e. employee (different education, different age, different culture, different habits), infrastructure (technology, age of the line, system implemented), and management (commitment and consistency). The main factors inhibit the implementation of GMP or prerequisite programs establishment could be lack of management commitment. For example, commitment related to quality and safety versus quantity, costs versus benefits, inconsistency and discipline, and attitude of people/personnel towards resistance to change.

Management review and evaluation of food safety management concluded that commitment, knowledge, attitudes and awareness of managements as well as of almost all workers were low. Consequently, the first step in establishing an effective prerequisite programs or implementation of GMP was to get commitment from management. It is essential that management understand the importance of having well written prerequisite programs that are understood and carried out by operators and quality control personnel. It was essential that management realize that this will take time and resources. In addition, management must be continually remaining effective.

Management of Food Safety System

As mentioned before, the attitudes of management toward HACCP management system are very important in the development of food safety implementation. The success or failure of food safety management depends on whether management supports the food safety

programs. At the beginning of the study the management of the case study factory seemed not having any interest in implementing a quality and safety assurance program, for a reason of time consuming and expensive. After having a better understanding about the concept, the management was asked to appoint a staff responsible on quality assurance (QA). This QA staff should report directly to top management, meanwhile the QA and production department should work closely together.

The success of food safety management especially of a HACCP system depends on educating and training management and employee in the importance of their role in producing safe foods (NACMCF, 1998). Based on this reference and evaluation results an educational training was designed for managers, supervisors and operators. The 4-days workshop was held before the tomato peak season. The short length of training may not give sufficient time to assimilate the information and develop individual HACCP plans. Despite of the limited time, there were improvements in sanitation and food hygiene practices and a variety of preventive measures were utilized from generic HACCP plan provided.

Potential Critical Control Points (CCPs)

Principally, the tomato sauce processing lines cover a simple steps as follows : Incoming materials (tomato, chili, sugar, salt, spices, vinegar), clean water, washing, sorting, heating and peeling, pulping, chopping and filtering, mixing pH 3-4; followed by boiling (cooking) 100°C for 60 minutes, filling (bottling) and sealing, pasteurization at 90°C for 20 minutes, cooling, labeling, packaging and storage. To ensure proper production in the case study tomato sauce industry, potential critical control points were identified based on hazard analysis and evaluation of hazards and critical control point's decision tree approach that developed by NACMCF (1998). The analysis resulted five potential critical control points (CCPs) as possible hazards that need to be controlled.

CCP 1 was identified as chemical hazards in the incoming materials (tomato and spices) as pesticide residue. All raw and packaging materials are purchased against specifications agreed with the list suppliers who are inspected, reviewed, and assessed annually on the base of raw materials quality and availability (Table 3). The acceptable limit of pesticide residue content is maximum 5 ppb (Pesticides Commission, Department of Agriculture). The pesticide residue is to be determined by using gas chromatography (GC) or high performance liquid chromatography (HPLC) depends on pesticides type. The analysis of pesticide residue is to be conducted once for every 4 months, using external laboratory. In case of non-conformity, the quality control manager should reject the incoming tomatoes and return to the suppliers.

Table 3. Specifications of incoming raw and packaging materials.

Items	Raw/packaging materials	Requirements
1.	Tomatoes - Sensory characteristics - Pesticide residue maximum - Foreign materials	 - Freshness and no foreign objects to the raw materials, based on SNI 01.3162-1992 requirements - 5 ppb (part per billion) - No foreign materials
2.	Salt	No foreign objects and based on SNI.01.3556-2000 requirements
3.	Sugar	No foreign objects and based on SNI.01.3140-2000 requirements
4.	Clean water	According to Ministry of Health requirements
5.	Spices (spices powder) - Maximum moisture content (w/w) - Pesticides of insecticides residue - foreign materials	Based on SNI.01.3709.1995 requirements. 12 % 5 ppb (part per billion) No foreign objects
6.	Vinegar (fermented vinegar) - Foreign materials - other requirements	 No foreign objects & certified suppliers Based on SNI .01.4371-1996 vinegar requirements
7.	Glass bottles	Certified suppliers, no foreign materials, bottles proper for foods
8.	Paperboard boxes	High or medium quality boxes from certified suppliers

CCP 2 was identified as microbiological hazards in mixing step of the raw materials. Mixing is critical because correct formulation has to be used in order to get a correct pH (3 – 4) and good quality and safety of the final product. It is therefore essential that an adequate pH was carefully controlled by trained operator to ensure that this condition was maintained for every batch of product. The monitoring records of the pH prior to heating and cooking have to be kept together with the formulation used.

CCP 3 was identified as microbiological hazards in step of cooking. Cooking constitutes as a critical control point (CCP) because of possible hazards for this step are of microbiological origin and are related to the possible growth and presence of the microorganisms in case of inadequate thermal process. Therefore, the conditions of cooking process are monitored and checked by trained personnel staff and checked by supervisor, so that the temperature and the time of cooking remain undergo within the prescribed critical limits, that is 100 – 105°C for 90 minutes. In either case, if considerable deviations are observed, the quality control manager orders a rejection or reprocess of that particular batch. In addition, one of the purposes of cooking is to eliminate vegetative cells of pathogens (or reduce them to acceptable level) that may have been introduced to the process by the raw materials or by processing that occurs before the cook step (ICMSF, 1996).

The cooked product of the final should have remained pH 3 – 4, therefore the vinegar is added towards the end of the cooking to replace the acetic acid that is lost by evaporator. Duration and temperature for cooking and concentration of the cleaning solution for the cooking equipment are checked and records are kept.

CCP 4 was identified as microbiological hazards in step of bottling and sealing. Bottling and sealing constitutes as a critical control point (CCP) because of the bottle to be used are supplied by certified suppliers and undergo on-line visual sufficient control for the detection of gross closure and glass defects (faults), including cap tilt, cooked cap, stripped cap and crack glass finish. The examinations should include cold water vacuum testing. In case of detected physical defects (cracks, faults, etc.) the bottles are rejected (CCP 4).

In addition, sealing is conducted by exerting air pressure onto the heading of the bottles. Fault seal on cap could allow re-contamination, therefore the seal on the cap should be correctly checked. In case of detected fault seal on the cap, the bottles are rejected (CCP 4). Visual control and examination of glass bottles at least one glass bottles from each sealing head at least every two hours of sealing machine operation. Records of visual examinations of glass bottles are kept.

CCP 5 was identified as microbiological hazards in step of pasteurization. Pasteurization constitutes a CCP, because some pathogens and vegetative and spore-forming bacteria such as *Bacillus* can survive in the product packed in the glass bottles, and able to multiplicate in the finished product container (ICMSF, 1998), so it can be of high risk for public health (Gilbert, 1992). The pasteurization process is carried out as a batch operation; the tomato sauce is heated in autoclave at 88–90°C for 20 minutes (CCP 5). The heat treatments aims at limiting public health hazards arising from pathogenic microorganisms (e.g. *Bacillus*) associated with low acids food (Al-Dujaili and Anderson, 1991; Jervis, 1992). Moreover, pasteurization extends the quality of tomato sauce by reducing the number of spoilage microorganisms.

The holding time for pasteurization must be very accurately determined. Preventive measure included: automatic system to prevent too low or too high temperature, extra cleaning if more 3 days have elapsed between processing runs and inspection of appropriate removal of tomato sauce residue. Thorough records of pasteurization temperature, deviations and undertaken corrective actions should be kept. Cleaning and disinfections procedures of the heating equipment are optimized and programmed.

Evaluation on Program of HACCP Implementation

Before implementation begins, appropriate training has been provided by this sauce company to all levels within the establishment. Training was focus on the knowledge and skill needed to carry out individual duties under the HACCP plan. Everyone in a facility does not

need to become a HACCP expert, but they should know their duties within a facility operating under HACCP. It is especially important that they know why those duties are important for food safety purposes.

The effectiveness of food hygiene and HACCP training in changing the knowledge, attitudes and practices of food handlers or workers were studied by some researchers. Some of the results points out the positive impact of training upon food handlers' or worker's knowledge (Cunningham, 1993; Manning, 1994; Sudibyo et al, 2001), while others have criticized traditional knowledge based training methods as having little impact on attitudes or behaviors (Ehiri et al, 1997). Results of the evaluation and judgment on educational training to the level of knowledge, attitudes and understanding of human resources in the case study industry are presented at Table 5. Training of employees resulted in greater awareness and compliance with appropriate personal hygiene and food handling practices. These behavior changes took time to achieve. It was significant that the company recognized the importance of training and its potential positive impact on employee behavior.

Table 4 shows a positive impact of the training to the attitude of human resources in all level of factory's management and staff. The enthusiastic of the management in implementing the HACCP system after understanding its important role in improving the overall quality of their product makes the following steps easier to implement. HACCP system for the case study industry was developed and implemented main steps as shown in Table 5.

The HACCP team consists of the following factory experts: (1) quality control and quality assurance manager (chemical engineer or food microbiologist), (2) production manager (food technologist/ chemist), (3) technical manager (mechanical engineer), (4) purchasing manager, and (5) production supervisor. The manager of the quality control (QC) department was appointed to manage basic responsibilities, he was the one who audit the records of controls, the corrective actions and responsible to cooperate with the consulting company. The QC manager participated in conducting a hazard analysis, developing the HACCP Plan and records (corrective actions, verification, and documentation) along with prerequisite programs sanitation procedures and records, and meetings with the external coordinators and trainers.

Based on observation and evaluation the company products (tomato sauce) is describe in Table 6. Tomato sauce is thick viscous liquids product that made from pulped of tomato with the addition of salt, sugar, spices and vinegar. They are pasteurized to give the required shelf life, but the basic principle of preservation is the use of vinegar, which inhibits the growth of spoilage and food poisoning micro-organism.

Implementation of HACCP system covered the improvement of prerequisite programs (GHP/GMP), training, operational changes and equipment purchases for compliance with the HACCP requirements. To improve the prerequisite programs the company invested in a wide variety of

Table 4. Changes of personals level of knowledge and understanding after food safety system training.

No.	Occupied or level status of management on the company	Level of knowledge, attitudes, and understanding on HACCP system for human resources from tomato sauce company							
		Before training				After training			
		Excel	Good	Fair	Poor	Excel	Good	Fair	Poor
1.	Production manager	-	V	-	-	V	-	-	-
2.	QC Manager	-	V	-	-	V	-	-	-
3.	QA Manager	-	V	-	-	V	-	-	-
4.	Head of laboratory	-	-	V	-	-	V	-	-
5.	Production Supervisor	-	-	-	V	-	V	-	-
6.	Production Controller	-	-	-	V	-	V	-	-
7.	Prod./Laboratory staff	-	-	V	-	-	V	-	-

Note: Excel = Excellence.

sanitation supplies and equipment for the individual needs of each operation. The use of sanitizers, cleaners, and employee supplies were re-evaluated. Investment were also used to replace inappropriate equipment such as hand wash stations, sinks, table, cutting boards, knives and other utensils. Investments were also used to repair infrastructures such as floors, walls, ceiling, and light fixtures to ensure compliance with GHP/GMP requirements. The re-evaluation of existing programs or services for pest control was also needed.

Since sanitation is one of the essential prerequisite programs for the successful implementation and maintenance of a HACCP program, a well written prerequisite programs known as Standard Operating procedures (SOPs) for sanitation regarding pathogen reduction and HACCP systems were established and developed. This written protocol includes: SOPs addressing the objectives, procedures and practices and job descriptions for individuals involved in carrying out a specific procedures outlined in the programs. The company's SOPs were also identified the position of the employee responsible for implementing and maintaining the SOPs, as well as the employee responsible for monitoring and evaluating the effectiveness of SOP and for taking corrective actions as needed.

During the first nine months of HACCP based inspections, internal auditors identified a large number of deficiencies in prerequisite sanitation requirements of the HACCP program. Many of the deficiencies were related to monitoring and record keeping requirements rather than inadequate practices. Inspections were generally designed to identify deficiencies, not to identify or recognize the type of improvements in infrastructure and equipment.

The tomato sauce company has made appropriate investments in equipment to enhance their ability to maintain proper pH value, proper temperatures and for monitoring devices for their process and products during storage. The company was installed also, a new complete product-testing laboratory for their operation. Thermometers and pH meter were purchased to monitor conditions in operation. These investments related directly

Table 5. Steps of HACCP Plan development and implementation in the medium scale of tomato sauce processing factory.

Steps	The activities that should be done for HACCP development and implementation
1.	Assemble /formation of the HACCP team
2.	Describe the food and its distribution
3.	Describe the intended use and consumers of the food
4.	Construction and develop a process flow diagram
5.	Verify the process flow diagram
6.	Conduct a hazard analysis (Principle 1)
7.	Establishment of CCPs applying the decisions diagram (Principle 2)
8.	Establishment of critical limits (Principle 3)
9.	Establishment of CCP monitoring procedures (Principle 4)
10.	Establishment of corrective actions (Principle 5)
11.	Establishment of verification procedures (Principle 6)
13.	Establishment of record keeping and documentation procedures (Principle 7)

Table 6. Product description

Company	Tomato sauce company
Company's management	Not applicable (NA)
Incoming raw material	Tomato
Product	Tomato sauce
Additives, raw materials	Salt, sugar, spices and vinegar
Packaging	Glass bottles (primary packaging), the product is automatically packaged under environmental conditions. Each 24 bottles is placed in corrugated boxes (secondary packaging)
Shelf life	2 years if the store in dry and cool room
Storage and delivery method	Storage and delivery under environmental conditions into boxes of particular standards due to glass brittleness.
Product use and sold	The products are ready for use without any further processing. The products are sold to export and domestic market
Consumers	General public

to the monitoring of specific control points, to provide option for corrective actions, or for use with the verification component of the HACCP system. The production stages, CCPs, occurring hazards and corresponding preventive measures, and the identified responsible personnel are presented in Table 7.

Costs of HACCP Implementation

Implementing and operating HACCP in the food factory requires a relatively big cost for improving the prerequisite and the system. Based on this study's experience there were two major costs, i.e. "cost for implementing and operating the HACCP" and "cost for maintaining the system" Detail cost as listed in Table 8 shows the total of Rp. 180 millions. This figure will be varied between factory.

There are two reasons that motivate the case study company to spend the money for implementing the system; those were to meet the customer and legal requirements, and to improve product quality and shelf life, as well as to reduce product failure and wastage.

Time Needed

The experience of this study gave a figure of the length time needed to prepare and implement the HACCP system in medium scale food factory, i.e. 12 months. This length of time was used for: (1) HACCP Plan development through consultation with external consultants, personal manager replacement and document preparation needed about 3 – 4 months; (2) HACCP plan implementation including the improvement of good hygiene practices or good manufacturing practices, investment in new equipment, training and education, and other HACCP requirements needed about 6 months; (3). HACCP maintenance needed 2 months, used for routine activities associated with the HACCP system, time to monitoring procedures to ensure that food safety hazards are under control as critical control point (CCP) at their operation, time devoted to records for monitoring required by the company's HACCP Plan, followed by sanitation records and the corrective action reports, and (4). HACCP certification process needed about 1-2 months.

Table 7. HACCP analysis for tomato sauce production in the tomato sauce factory, Tangerang, Banten.

Critical Control Point (CCPs)			Monitoring of CCPs			Corrective Actions	Identity of responsible personnel
Stage	Hazards	Critical limits	Method	Frequency	Recording		
1. Incoming raw materials	• Microbiological	E. coli < 10^3; B. cereus = 10^4 CI; Pathogens <10^2 (CFU)	According to specified directives, visual control for molds presence or other bacterial spoilage and microbiological control	Once for every 4 months for verification	Incoming materials control files	Rejection of batch	Quality control manager
	• Chemical	Pesticides residue content maximum 5 ppb according to ministry of agriculture and ministry of health regulation	Toxicological control with GC (Gas Chromatography) or HPLC (High Performance Liquid Chromatography)	Once for every 4 months for verification	Incoming materials control files	Rejection of batch	Quality control manager
2. Mixing	• Microbiological contamination and molds	No contaminated species No molds pH 3 - 4	Check the correct pH Check correct ingredient weight & formulation Visual inspection	Twice for every batch	Mixing control files	Rejection of batch or segregate product	Production supervisor
	• Physical	No foreign objects	Visual inspection	Twice for every batch	Mixing control files	Rejection of batch or segregate product	Trained personnel
3. Cooking	• Microbiological	Temperature 100-105°C Time 90 minutes pH ; 3 - 4	Check correct temperature. Check correct time Check correct pH	Continuos for every batch Twice for every batch	Cooking control files	Rejection of batch or reprocess of the specific batch cooking To longer time of cooking	Trained personnel and verify by QC manager
4. Bottling & Sealing	• Microbiological contamination	No leakage of bottle and cool	Visual inspection Test of leakage for bottles and seal by water vacuum testing	Twice for every batch	Bottling and sealing control files	Rejection of batch	Trained personnel
	• Physical	Bottles proper for foods; No undesirable foreign materials & particles, cracks or scratches	On-line visual control, supplier certificate	Continually, each bottle is separately examined	Packaging materials quality control files	Rejection of faulty bottles (not used for bottling)	Trained personnel
5. Pasteurization	• Microbiological (pathogens)	Temperature : 88 -90°C Time : 20 minutes	Check the correct temperature & time on line monitoring	Continue for every batch	Pasteurization control files	Rejection of batch or reprocess of the specific pasteurization Recalibrated the thermometer	Supervisor and quality control manager

Table 8. Cost for implementing and operating the HACCP system

No	Activity	Cost, Rp.
I	Cost for implementing and operating the HACCP system	145,000,000
	• External consultants	15,000,000
	• Investment in new equipment and improving GMP facilities	100,000,000
	• staff training and education	10,000,000
	• managerial changes	10,000,000
	• structure change to plant	5,000,000
	• staff time in documenting system	5,000,000
II	Cost for maintaining the system	35,000,000
	• monitoring	5,000,000
	• sampling and testing	10,000,000
	• cost associated with process modification	10,000,000
	• Others	10,000,000
	TOTAL	180,000,000

Quality and Safety Auditing

Through consultation and assistant given during this research, the company completed documents and records as required by HACCP system, including: (1) HACCP plan, current state and history of amendments; (2) monitoring and keeping records of CCP measurements, deviations and undertaken corrective actions; (3) hold/trace/recall records in case of deviations, (4) training records to show that personnel is well trained, (5) auditing records for non-conformance cases; and (6) calibration record related to instrumentation. The records are in typed format and are kept either on a daily basis (CCP measuring) or whenever the needs arises (corrective actions) and are filled for a minimum period of 2 years.

Internal audit was also carried out to ensure the proper functioning of the system. In this factory audit in one department was carried out by the head of another department. Internal audit was conducted every four months and records were kept for future reference. In case of out specifications occurring situations, i.e. high/lower temperature, detailed records were kept describing the problem and its causes. Corrective actions were predicted for each CCP in case of deviation as properly described at each stage for individual CCPs.

The quality and safety audit was conducted by Australian Institute of Environmental Health (AIEH) Australia with Center of Agro Based Industry (CABI) as an observer. It was concluded that the case study factory was complied with the HACCP Plan and prerequisites, and their implementation met regulatory requirements.

CONCLUSIONS

The conclusion of this study was as follow:

1. In general, the existing conditions of tomato sauce factory prior to implement HACCP were not met the prerequisite programs and management on food safety system. This company needed to establish and develop the SOPs, improve the GHP/GMP facilities, conduct training and education for the staff, change the operation or modify the process, and purchase equipment for compliance with HACCP requirements.
2. Five potential critical points were identified as known CCPs that needed to be controlled in order to produce safe tomato sauce. These potential CCPs were: the incoming material, mixing at pH 3-4 values, heating/cooking, bottling and sealing, and pasteurization.
3. Program of HACCP implementation consists of establishing and developing the SOPs, employee training and education, improvement of GMP facilities like for infrastructure, a wide variety of sanitation supplies and equipments for the individual needs of each operation, investment in equipments to enhance their ability to maintain proper pH value, proper temperatures, and for monitoring devices in their process and products.
4. Implementation of HACCP system in the medium scale of tomato sauce factory needed total cost of around 175 millions rupiah. The time needed since starting to plan the system until fully operational was about 12 months.
5. The modules used in this case study can be adopted as a generic model of HACCP implementation system in the other similar factory.
6. To fulfill the requirement of food safety management and HACCP system the

medium scale food industry in Indonesia still needs to improve its basic condition. More intensive socialization to food processors for their better understanding on food safety and HACCP is urgently needed.

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