Case Report

The implementation of HACCP management system in a chocolate ice cream plant

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\textbf{A B S T R A C T}

To guarantee the safety of chocolate ice cream production, the Hazard Analysis Critical Control Points (HACCP) system was applied to the production process. The biological, chemical, and physical hazards that may exist in every step of chocolate ice cream production were identified. In addition, the critical control points were selected and the critical limits, monitoring, corrective measures, records, and verifications were established. The critical control points, which include pasteurization and freezing, were identified. Implementing the HACCP system in food manufacturing can effectively ensure food safety and quality, expand the market, and improve the manufacturers' management level.

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1. Introduction

HACCP, which stands for Hazard Analysis and Critical Control Point, is defined as a "Food Safety Control System" in Taiwan's food hygiene legislative system [1]. It stresses on—through critical hazard control—reducing or eliminating hazards to the lowest level during the processing steps, while establishing critical limits, monitoring procedures, corrective measures, records, and verifications. HACCP is a further feature of the presented quality guarantee method based on standard operating procedures, Good Manufacturing Practice, and Good Hygiene Practice in Taiwan [2]. It has two major components: hazard analysis and critical control. Hazard analysis is primarily about systematically identifying and assessing the food production process, and selecting any "biological", "chemical", and "physical" characters or factors that may render the food unsafe. Critical control is mainly about basing on the results of hazard analysis, and formulating and managing the...
controllable points or procedures during the process to minimize the safety hazard of final products (Table 1) [3].

HACCP is a world-recognized, effective, and preventive food hygiene management system. At present, the HACCP system has been widely adopted by many countries such as the United States, Japan, the United Kingdom, and member states of the European Union, as well as international organizations such as the World Health Organization, Food and Agriculture Organization, and Codex Alimentarius Commission (CAC) [4]. In Taiwan, exported products were obliged to meet the requirements established by American regulations on fish and fishery products; thus, fish and fishery products became the first food industry that was required to perform mandatory HACCP practices [5]. In consideration of the booming development of the catering industry and the increasing number of food poisoning incidents, the Department of Health, Executive Yuan started to promote the development of HACCP practices stage by stage—from encouraging voluntary application to mandatory implementation [6]. Nowadays, fish and fishery products, meat products, meal box, and dairy products are required to perform mandatory HACCP practices; meanwhile, an increasing number of food processing manufacturers are voluntarily applying for HACCP certification.

Because of the plasticizer addition scandal in 2011 and the maleic acid incident in 2013, the Taiwan food industry encountered a serious crisis that shook the consumers’ confidence toward food corporations and government regulatory bodies, resulting in remarkable reputation damage and financial losses [7]. Traditional quality ensuring methods, which simply require inspecting the final products, can no longer satisfy the consumers’ needs. Implementing HACCP is helpful in gaining consumers’ trust and establishing a good corporate image. Moreover, many countries such as the United States, member nations of the European Union, and Japan have strict requirements regarding food imports [8]. The application of HACCP enables corporations in Taiwan to break down trade barriers and participate in international business, thereby effectively expanding their markets and increasing profits. Additionally, a logical and applicable HACCP plan can help food factories improve their management level and enhance their staff’s safety consciousness.

Chocolate ice cream is a frozen food that uses dairy products, cocoa powder, and chocolate chips as main ingredients, mixing them with sugar or syrup, egg products, emulsifier, stabilizer flavors, and colors, produced through a series of processing steps. In Taiwan, ice cream is a huge industry that accounts for a market share of approximately NTD 1688 million, representing 2115 tons of products sold for the year 2012 [9]. Chocolate is the second favorite ice cream flavor in Taiwan, after vanilla [10]. Chocolate ice cream is a good microbial growth medium because of its nutrients (lactose, protein, carbohydrate, etc.) and neutral pH profile [6,7]; however, its quality is difficult to determine solely by appearance. Therefore, preventing microbial contamination has been crucial for its safety control. HACCP has been proven to be effective in inhibiting the growth of Staphylococcus aureus, Escherichia coli, and other human pathogens in chocolate ice cream production [11]. The quality and safety of the final product can be effectively guaranteed through the application of the HACCP system (Table 2) [13].

2. Materials and methods

2.1. Study object

The entire production process of chocolate ice cream was evaluated including the plant layout, structure of each facility, technical standards, facility cleansing method, staff assignment, safety control method, condition of storage, and distribution (Fig. 1). The potential biological, chemical, and physical hazards that may exist in every step of the production process were identified, and then critical control points (CCPs) were selected.

2.2. Methods

Based on the Department of Health, Executive Yuan’s regulations revised in 2008: Food Safety Control System, United Nations Codex Alimentarius Commission’s HACCP and guidelines for its application (revision of 2003), the overall technical process of chocolate ice cream production was drawn, and a hazards analysis was performed. CCPs were subsequently selected. Based on government regulations and industry standards, critical limits were established, as well as monitoring procedures, corrective measures, records, documentations, and verifications. The decision tree method was implemented to select the CCPs. This method is a visual, easy-to-understand alternative to the numerical charts and statistical probabilities in other decision analysis methods, such as hazard analysis scheduling and spreadsheets.

3. Results and discussion

The overall flow diagram of the chocolate ice cream technical process is summarized in Fig. 2, including receiving of raw materials, weighing and mixing (liquid and solid), sifting, homogenization, pasteurization, cooling, aging, freezing (following chocolate chip addition), packaging, hardening, and storage/distribution.

3.1. Hazard analysis and prevention measures establishment

From the receipt of materials to the delivery of the final products to every retailer, hazard analysis was performed at every technical procedure to define any biological, chemical, and physical factors that may affect food safety. The severity and risk will determine the significance of each hazard.

3.1.1. Acceptance of raw material

Milk and other dairy products can provide ice cream with fat content and nonfat solids, giving ice cream its distinctive flavor, soft mouth feel, and rich nutritional materials. Additionally, fresh cream offers various kinds of fine lipid, which enhances the smooth mouth feel of the final product [12]. Each type of dairy products should meet the requirement of the Chinese National Standards (CNS), for example, standard CNS NO.2343 for milk powder and CNS NO.2878 for milk cream. General dairy products must meet the requirement of
| Technical process | Hazard factors | Significant or not | Criteria for judgment | Prevention and control measures | Critical control point |
|-------------------|----------------|--------------------|-----------------------|--------------------------------|------------------------|
| Acceptance of raw materials | **B** Escherichia coli, *Listeria monocytogenes*, *Salmonella* spp., *Staphylococcus aureus* | No | Suppliers’ inappropriate technical process, or inappropriate storage and distribution, may cause microorganism contamination | Demanding for business license and product inspection report from the supplier | CCP1 |
| | **C** Antibiotics, aflatoxin, nitrate, nitrite | Yes | Dairy farmers do not stop using antibiotics a certain number of days prior to milking, therefore raw material may contain antibiotic content Harmful chemicals may get in the material due to suppliers’ inappropriate production process | Sampling and examining for every batch of material The suppliers should provide a self-evaluation document to ensure the materials were not contaminated by pathogens or toxins | |
| | **P** Stone, metal | No | Brought in by suppliers during production, storage, transportation process | Sifting and metal detection in the following procedures | |
| Weighing and mixing | **B** Microorganism contamination and growth during weighing, feeding and mixing process | No | Inappropriate feeding temperature and sterilization on mixing vat, may result in microorganism contamination | Quickly perform feeding process at low temperature Mixing vat should be clean and sterilized in advance to ensure no pathogen left Designing formula strictly under the requirement of *Standards for Specification, Scope, Application, and Limitation of Food Additives* | |
| | **C** Excessive food additives | No | Excessive food additives may be harmful to human health | Regularly correct weighing facilities Keeping production environment and facilities clean Sifting and metal detection in the following procedures | |
| | **P** Metal residue | No | Metal may left at weighing and mixing facility | | |
| Pasteurization | **B** Living pathogen left after pasteurization | Yes | Inadequate pasteurization | Strictly control pasteurization time and temperature | CCP1 |
| | **C** None | No | N/A | N/A | |
| | **P** None | No | N/A | N/A | |
| Aging | **B** Microorganism contamination and growth | No | Microorganism growth may occur due to extra-high aging temperature, extra-long process, or extra-slow cooling Inappropriate facility sealing may also results in contamination | Strictly control aging condition, keep relevant facility clean and sealed | |
| | **C** None | No | N/A | N/A | |
| | **P** None | No | N/A | N/A | |
| Freezing (+ adding chocolate chips) | **B** Microorganism contamination and growth | Yes | Chocolate chips and large amount of air is incorporated thus pathogen may contaminate | Keep the inlet and its surrounding air clean, filter screen must sterilized in advance, chocolate addition need to be performed quickly at a low temperature | CCP2 |
| | **C** None | No | N/A | N/A | |
| | **P** None | No | N/A | N/A | |

*B* = biological; *C* = chemical; *CCP* = critical control point; *N/A* = not applicable; *P* = physical.
| Critical control point | Significant hazards | Critical limits | Monitoring | Corrective measures | Records | Verification |
|-----------------------|---------------------|-----------------|------------|---------------------|---------|--------------|
|                        |                     |                 | Object     | Method              | Frequency | Personnel    |             |
| Pasteurization (B)     | Living pathogens   | Keeping         | Temperature | Automatic           | Every vat | Operator     | Second time pasteurization |
|                        | left                | pasteurization  | Time       | temperature controller | Operator |             |                |
|                        |                     | temperature at  |            |                     |          |             |                |
|                        |                     | 80–85 °C,       |            |                     |          |             |                |
|                        |                     | maintaining the |            |                     |          |             |                |
|                        |                     | temperature for  |            |                     |          |             |                |
|                        |                     | 15 min          |            |                     |          |             |                |
| Freezing (+adding      | Pathogen           | Good Hygiene    | Factory sanitary | Cell culture       | Every batch | Operator; Hygiene | Factory structure need to be modified if its design contains major defect |
| chocolate chips) (B)   | contamination and growth | Practice     | condition; chocolate adding process |              |           | management personnel |                |
|                        |                     | Ice food       |            |                     |          |             |                |
|                        |                     | factory good   |            |                     |          |             |                |
|                        |                     | manufacturing   |            |                     |          |             |                |
|                        |                     | practice,      |            |                     |          |             |                |
|                        |                     | processing     |            |                     |          |             |                |
|                        |                     | should be      |            |                     |          |             |                |
|                        |                     | located at     |            |                     |          |             |                |
|                        |                     | “clean operation area” |        |                     |          |             |                |
|                        |                     | 55–60 °C, 3%     |            |                     |          |             |                |
|                        |                     | sodium         |            |                     |          |             |                |
|                        |                     | hydroxide      |            |                     |          |             |                |
|                        |                     | wash, on: pipe  |            |                     |          |             |                |
|                        |                     | entrance and   |            |                     |          |             |                |
|                        |                     | inner wall, vat.|            |                     |          |             |                |
|                        |                     | 93 °C water     |            |                     |          |             |                |
|                        |                     | wash for 10–15  |            |                     |          |             |                |
|                        |                     | min [13]        |            |                     |          |             |                |

B = biological hazards; HACCP = Hazard Analysis and Critical Control Point.
Department of Health: Dairy Hygiene Standard. Egg products contain a large amount of lecithin. Serving as an emulsifier and stabilizer, lecithin gives ice cream a smooth and stable texture and flavor [12], and it should meet the limits set by the Department of Health: Egg Product Hygiene Standard. Moreover, egg suppliers are required to submit salmonella inspection reports. As a major ingredient of ice cream, water should meet the provisions of Environmental Protection Administration: Drinking Water Quality Standards. Overall, the chocolate ice cream final product should contain over 8% of milk fat, 30% of solid content, and 2.6% of milk protein [13]. The microbiological quality of ice cream should be low, as it is a rich growth medium for microbes. There are numerous reports on the incidence of human pathogens in ice cream, such as Listeria monocytogenes, Salmonella species, Staphylococcus aureus, and Bacillus cereus [11,14–16]. Raw material suppliers are required to submit quality inspection reports. Every batch of material should be sampled and inspected.

3.1.2. Material mixing
After each material is weighed based on the chocolate ice cream formula, the materials are then mixed in a certain order according to the technical requirement. Liquid milk will be initially added into the mixing vat. Sugar, milk powder, food

Fig. 1 – Large ice cream plant for production of 5000–10,000 L/h of various types of ice cream. Reproduced with permission from Reference [18], ©Tetra Pak.
additives including flavors and colors, and other solid materials will be fully dissolved in water in another vat, then added to the mixing vat and fully mixed with milk. The feeding process must be conducted at a sanitary environment; the mixing vat should be fully cleaned and sterilized in advance to ensure that no pathogen is left.

Food additives include emulsifiers, stabilizers, flavors, and colors. Emulsifiers have both hydrophobic and hydrophilic units; thus, they can break the resistance of fat globules, keeping fat and water together. Stabilizers have strong hydrophobicity and can prevent the migration of unfrozen water, thereby preventing the final product from forming large ice crystals and a coarse structure, which contributes to the viscosity of the ice cream. Additives must fulfill the requirements of the Department of Health: Standards for Specification, Scope, Application and Limitation of Food Additives [5].

3.1.3. Homogenization
By homogenizing the mixed material, ice cream can gain a fine and smooth mouth feel and stable texture. Homogenization can increase the overrun [\(\%\text{Overrun} = (\text{Vol. of ice cream} - \text{Vol. of mix used})/\text{Vol. of mix used} \times 100\%\)] and reduce ice crystallization within the ice cream [12]. It should be performed under a strict temperature- and pressure-controlled environment.

3.1.4. Pasteurization
Appropriate pasteurization will kill most food-borne pathogens. An extra-high temperature can damage the materials’ nutrients and bioactivity, and affect the flavor of the final product; by contrast, an extra-low temperature will not be able to sufficiently eliminate the pathogens [12].

During the final product testing, where a 1-mL sample is melted in water, the viable bacterial count should be less than 30,000, and the coliform bacterial test result should be negative [13].

3.1.5. Aging
The purpose of aging is to make protein, lipid, emulsifier, and stabilizer fully expand with water, optimize the foamability of mixed materials, and increase viscosity. Time and temperature must be carefully monitored during the aging process. Pasteurized materials must be quickly cooled down to approximately 0–4 °C. The aging process takes about 4–24 hours. Pathogens can grow in the temperature range of 20–38 °C; therefore, the cooling rate must be maintained at a high level [17]. To prevent microorganism contamination, the aging facilities must be carefully sealed.

3.1.6. Freezing
The process of freezing involves intensely blending aged materials; therefore, tiny air bubbles will be added and evenly distributed in the material. Thus, the material will become half-frozen and further expand to gain a fine texture and shape. Ice cream that is not sufficiently frozen will eventually present as tasteless and hard. Nonfat solid from the milk material enhances the chew resistance and holds the air during freezing. Generally, an ice cream final product contains 8–10% nonfat solid. Sugar not only contributes to the sweetness but also lowers the freezing point, thus preventing the ice cream from becoming too hard. However, excessive sugar addition will reduce overrun and affect the overall texture and taste. An appropriate sugar content ranges from 12% to 16% [12].

Following the half-frozen procedure, chocolate chips are added and evenly stirred. The air pumped into the material must be sanitary, thus requiring the processing environment and the facility to be clean. Based on the provisions of Ice food factory good manufacturing practice, the freezing procedure should be performed at a “clean operation area” to prevent bringing in pathogens from the air, meaning the area needs to be fully isolated from other environments. Personal hygiene needs to be carefully checked prior to when personnel can enter the area, and a special unit for preventing the entry of dust and insects should be installed. Meanwhile, chocolate chips should also be added quickly under a low temperature environment to prevent microorganism contamination.

3.1.7. Hardening
After being packaged, the product needs to be processed through a certain period of low temperature freezing. The water content will be fully crystallized, and the shape of final
product will be fixed. The hardening process must be performed within a short period, or any temperature rise will cause melted crystals to agglomerate and form large ice crystals after hardening. Normally, hardening lasts for 12–24 hours in −25°C to −18°C [12].

3.2. Establishing CCPs and critical limits

Based on the result of hazard analysis, the chocolate ice cream production process contains two CCPs. Critical limit is the processing requirement that needs to be fulfilled at every corresponding control point. The HACCP system is applied in the present study as a preventive food safety approach to control the potential hazards appearing in the ice cream production plants in Taiwan. Most of the proposed CCPs in ice cream production were mainly attributable to improper handling and practices throughout the processing steps and also to the lack of food hygiene knowledge among the workers.

3.2.1. CCP1 pasteurization

The first CCP suggested in this study was the pasteurization process. Pasteurization temperature should be maintained at 80–85°C, and the temperature needs to be maintained for 15 minutes [17]. Inadequate pasteurization may allow the pathogens to remain and grow, whereas extra-high temperature or extra-long pasteurization may negatively affect product quality.

3.2.2. CCP2 freezing and chocolate chip addition

The third CCP was the freezing and chocolate chip addition process. Freezing facilities should be located in a “clean operation area”, where factory environment, personal hygiene, and presence of dust and insects are strictly controlled. Facilities need to perform standard clean-in-place procedures to ensure that air incorporated into the ice cream remains sanitary [17,18].

The microbiological quality of ice cream can be low, as it is a good growth medium for microbes because of its nutrients (lactose, proteins, etc.) and to its almost neutral pH of 6–7 [19]. HACCP is a systematic approach used in the food industry for the identification, assessment, and control of biological, chemical, and physical hazards [3], providing an effective way to advance food quality/safety, focusing on preventing hazards and improving processes [20].

3.3. Establishing monitoring procedure

To guarantee that the critical limit established at every CCP can be continuously fulfilled, a monitoring procedure must be established in the HACCP system. The monitoring procedure contains the following factors: object, such as additive quantity; method, such as demanding for inspection report; frequency, such as every batch; personnel, such as operators.

3.4. Establishing corrective measures, verification, record, and documentation

In order to prevent unsafe products from reaching consumers, a corrective action is carried out when there is a deviation from any established CCP. During this procedure, problems will be corrected and production will be put back in control. Any unqualified product will be further tested to determine its safety. A complete HACCP plan also requires a verification procedure, such as random sampling and testing, to examine whether HACCP can effectively control food safety. Additionally, the implementation of the HACCP system should be well documented. Documentation usually includes the content of hazard analysis and CCP determination, and record-keeping includes CCP monitoring activities, deviation and associated corrective actions, and verifications. These procedures help to verify that HACCP controls are in place and are being appropriately maintained.

4. Conclusion

The hazards in chocolate ice cream production are mainly attributable to the use of excessive food additives, inappropriate processing conditions, and unsanitary manufacturing environment [21]. The results of this study showed the extent of the positive effects that a HACCP system—introduced in a chocolate ice cream factory—had on both the microbiological quality of the final product and on the total quality/hygiene management. The application of the HACCP system provides food manufacturers with effective preventive methods to guarantee food safety and improve management. Additionally, the documentation and records generated in the HACCP system can easily help in tracing the origin of contamination, thus preventing further production of substandard products and lower the consumption of manpower, material, and financial resources. At present, HACCP is difficult to implement in some manufacturing plants because of technical and financial obstacles. Although most of the major manufacturers have applied HACCP for ice cream production, the problems come from the point of sale. For instance, retailers in night markets, which are a unique feature of Taiwanese culture, may lack enough knowledge of hygiene, resulting in the contamination of the ice cream. Therefore, this measure requires government support for its wider application. Further linkage of the HACCP system introduced in the factory to quality management systems, such as International Organization for Standardization regulation, can be possibly proved to provide higher quality/hygiene standards, along with higher awareness among the factories’ customers (i.e., ice cream retailers).

Conflicts of interest

All authors declare no conflicts of interest.

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REFERENCES

[1] Department of Health, Executive Yuan, R.O.C. (Taiwan). Food Safety Control System (HACCP). Available at, http://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&lang=1&lawid=38; 2007 [accessed 31.03.13].

[2] Jeng HY, Yang JT. Food safety control system in Taiwan – the example of food service sector. Food Control 2003;14:317–22.

[3] United Nations Codex Alimentarius Commission’s Hazard analysis and critical control point (HACCP) and guidelines for its application. Annex to CAC/RCP 1-1969 (Rev. 4-2003). Available at:http://www.mhlw.go.jp/english/topics/importedfoods/guideline/dl/05.pdf. [accessed 02.04.13].

[4] Meng L, Yang Q, Cheng J, et al. Study on the application of HACCP system in ice-cream premix powder processing. J Anhui Agric Sci 2011;39:6531–3.

[5] Food and Drug Administration, Department of Health, Executive Yuan, R.O.C. (Taiwan). HACCP certificated corporation list — Food safety control system of catering industry. Available at: https://consumer.fda.gov.tw/Pages/detail.aspx?nodeID=59&pid=4961. [accessed 01.07.13].

[6] Hsu CK, Hsiao SY, Cheng WC, et al. The progress of HACCP certificated program carried out in food and beverage industry in Taiwan. Ann Rep Food Drug Res 2011;2:77–82.

[7] Kao YM. A review on safety inspection and research of plastic food packaging materials in Taiwan. J Food Drug Anal 2012;20:734–43.

[8] Zhu J, Yuan K, Zhang Y. Present status of food safety and application foreground of HACCP. Food Sci 2003;14:260–4.

[9] Department of Statistics, Ministry of Economic Affairs. 2012 yearbook of industrial production statistics, Taiwan area, the Republic of China. p. 154. Available at, http://2k3dmz2.moea.gov.tw/Gwweb/default.aspx?menu=ebook&book=indvalue_y; 2013 [accessed 14.04.13].

[10] Euromonitor International. Packaged food: Euromonitor from trade sources/national statistics; 2013. Retrieved from Euromonitor Passport GMID database.

[11] Kokkinakis EN, Fragkiadakis GA, Ioakeimidi SH, et al. Microbiological quality of ice cream after HACCP implementation: a factory case study. Czech J Food Sci 2008;26:383–91.

[12] Li W. Manufacturing engineering of the ice cream. Zhongguo Gong Xiao Shang Qing (Dairy Guide) 2005;4:23–6.

[13] Bureau of Standards, Metrology and Inspection. Chinese national standards for packaged ice cream; 2011. Retrieved from CNS online database.

[14] Vought KJ, Tatini SR. Salmonella enteritidis contamination of ice cream associated with a 1994 multistate outbreak. J Food Prot 1998;61:1493–6.

[15] Massa S, Podan G, Cesaroniz D, et al. A microbiological survey of retail ice cream. Food Microb 1989;6:129–34.

[16] Torkar KJ, Mozina SS. Differentiation of Bacillus cereus isolates from milk and milk products with biochemical, immunological, AP-PCR and PCR–RFLP methods. Food Technol Biotechnol 2000;38:135–42.

[17] Zhong Z. Application on the HACCP management system in ice-cream production. Food Eng 2012;1:56–9.

[18] Bylund G. Dairy processing handbook. Lund, Sweden: Tetra Pak Processing System AB; 1995, pp. 392–3.

[19] Kanbakan U, Con AH, Ayar A. Determination of microbiological contamination sources during ice cream production in Denizli, Turkey. Food Control 2004;15:463–70.

[20] Swanson KM, Anderson JE. Industry perspective on the use of microbial data for HACCP validation and verification. J Food Prot 2000;63:815–8.

[21] El-Tawila MM. The application of the hazard analysis and control points (HACCP) in an ice cream production plant. J Egypt Public Health Assoc 1998;73:193–217.