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RESEARCH REVIEW

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The Hazard Analysis and Critical Control Point (HACCP) System and Its Implementation in an Aseptic Thermal Juice Processing Scheme: A Review

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Abstract Hazard Analysis and Critical Control Point (HACCP), a systematic process that identifies, assesses, and controls hazards, has been developed as an effective alternative to conventional end-point analysis for food safety control. The importance of HACCP has been emphasized recently due to the development of new food processing technologies and the increase in international trade demanding worldwide of food product safety. This paper provides a review of HACCP and a generic HACCP template for its implementation for aseptic processing of a juice drink.

Keywords: HACCP, aseptic processing, juice processing, GMP, hygiene

Introduction

Hazard Analysis and Critical Control Point (HACCP) is a management system used to analyze and control biological, chemical, and physical hazards that may result from harvesting, processing, manufacturing, distributing, or preparing food for consumption (1). The HACCP concept was originally developed to produce microbiologically safe foods to be used in space in the 1960's by the Pillsbury Company working with NASA and the U.S. Army Laboratories in Natick (MA, USA) (2). The U.S. Food and Drug Administration (FDA) is currently applying it to seafood, juice, and dairy products. The agency is currently considering the development of regulations that would establish HACCP as the food safety standard for other foods, including both domestic and imported food products (3). HACCP has been identified as a potential component of the international standardization of food quality and safety control and assurance (1). The HACCP system is compatible with the implementation of total-quality management systems based on the international organization for standardization (ISO) 9000 series of standards (4).

Most industries and regulators have depended on spot-checks of manufacturing conditions and random sampling of final products to ensure the safety of foods (4, 5). The major limitations of end-point tests include: (i) end-point tests give information about the tested hazards only; (ii) the only corrective action is the rejection of the final products, which is inefficient in terms of wasted ingredients and production time; (iii) a significant amount of a food product has to be sampled for analysis, especially when contaminants are not evenly distributed; (iv) any contaminations or defects resulting from distribution and handling are not accounted for during testing (6). HACCP has been developed as an alternative to end-point tests (7). HACCP focuses on the prevention rather than detection of problems in the final products by controlling and minimizing routes of contamination (4, 7).

The FDA adopted final regulations that mandate the application of HACCP principles to ensure the safe and sanitary processing of fruit and vegetable juices (8). Since food pathogens, such as *Escherichia coli* O157:H7 and *Salmonella*, can survive in apple and orange juices in their native relatively acidic environment at refrigerated temperatures, the juice products can function as a vehicle for transmitting food pathogens (4, 9). Recent illness outbreaks associated with non-pasteurized apple ciders occurred in Ohio, USA in 2003 and in New York, USA in 2004. Multi-state illness outbreaks due to non-pasteurized orange juice occurred in 2005 (4). Chemical and physical hazards are also likely to occur in juice products because these products may include diluting and sweetening processes to make them palatable as beverages. When hydrogen peroxide is applied for sterilizing aseptic packaging systems, the residual hydrogen peroxide must be addressed as a chemical hazard (1, 10). All of these issues emphasize the need for HACCP to ensure that each step in juice production is appropriate and safe.

Commercial aseptic processing and packaging involves the use of continuous closed systems to produce food products with a longer shelf life at lower energy expense than traditionally canned food products (11). This technology has been widely used commercially in many countries (12). However, no HACCP plans for aseptic food processing have been reported in scientific papers. The objectives of this paper are to (i) present an overview of the implementation of HACCP and (ii) develop a generic HACCP template for aseptic thermal juice processing employing steam and hydrogen peroxide as the sterilizing media. The model product used is a 10% orange juice drink. This template is intended to be used as a guideline for the development of diluted juice-specific HACCP procedures.

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Prerequisite to HACCP

A prerequisite program needs to be in place before HACCP implementation. The objective of prerequisite programs is to produce basic environmental and operating conditions for the production of safe and wholesome food (13). The programs should provide an essential foundation for the development and implementation of successful HACCP plans. The prerequisite programs begin with the proper selection of equipment and design of production lines to minimize cross-contamination from raw to cooked products. Common prerequisite programs include Good Manufacturing Practices (GMP), Sanitation Standard Operating Procedures (SSOP), hygiene plans, workforce training programs (e.g., personal hygiene training), product formulations, appropriate utilities, chemical control, glass control, receiving, storage, and shipping under sanitary conditions, lot-coding for the complete tracing and recall of products, labeling, waste disposal procedures, and pest controls (4, 10, 14). All prerequisite programs should be documented and managed separately from the HACCP plan (4, 13).

Conducting GMP during processing avoids recontamination with pathogenic microorganisms such as *Staphylococcus aureus* and *Listeria monocytogenes*, mainly carried by food handlers (4, 14). The SSOP emphasizes sanitation conditions and practices during receiving, storing, preparing raw materials, and processing to ensure proper handling and to maintain a food facility with a clean and sanitary environment (4, 14, 15). If sanitation conditions and practices are not met, processors must take corrective actions because unsanitary conditions can directly result in biological hazards (4).

In accordance with GMP for aseptic food processing (10), compressed air must be free from oil, excessive dust, moisture, or contaminating vapors. Some aseptic food processing systems employ filters (e.g., HEPA; HEPA Corp., Anaheim, CA, USA) to provide sterile air to aseptic packaging filler units. The filters are also used to produce sterile gases for steam removal, overpressure, nitrogen flush, peroxide transport, and drying. Hydrogen peroxide for sterilization must be compliant with 21 CFR Section 178.1005 on hydrogen peroxide solutions and meet the Food Chemical Codex requirements. Steam is used to sterilize products or product contact surfaces directly. A steam purifier is used to remove residual condensate, oil, and solid impurities. Water must be safe and of an adequate sanitary quality for juice production (1). Processors must examine the source of water used in their facilities and determine the necessary provisions to ensure the safety of water, which includes filtration and deionization (1, 10). In the USA, water must be in compliance with 141, 142, and 143 of Title 40, Code of Federal Regulations, along with any additional state and local codes (10). All sanitary piping, fittings, and connections must be smooth, impervious, nonabsorbent, corrosion-resistant, nontoxic, and easily cleanable. Internal joints must be smooth, continuous, and free of crevices (10). Improperly designed and constructed equipment can result in inappropriate cleaning-in-place (CIP) practices. The roughness of the stainless steel surfaces is the most important factor determining the effectiveness of cleaning biofilms from surfaces (10). Biofilms are a community of multiple microbial cultures anchored to a substratum and embedded in an organic polymer matrix, which is a reservoir of microorganisms (14). The biofilm can cause post-processing microbial contamination (16). Sharma and Anand (16) collected samples for biofilm analysis from different segments of milk pasteurization lines from a commercial plant after CIP and their microbial analysis provided evidence of the existence of biofilms even after CIP. The type and concentration of a sanitizer must be carefully selected for the effective reduction of biofilms (2). The evaluation of biofilms must be part of a HACCP plan.

The FDA encourages farmers and juice processors to evaluate and modify their agricultural practices in accordance with FDA's 'Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables' (1), which describes basic principles and practices associated with minimizing microbial food safety hazards from the field through the distribution of fresh fruits and vegetables (2).

HACCP principles

HACCP involves seven principles (9, 15, 17): (i) conduct a hazard analysis, (ii) identify critical control points, (iii) establish preventive measures with critical limits for each control point, (iv) establish procedures to monitor the critical control points, (v) establish corrective actions to be taken when monitoring shows that critical limits have not been met, (vi) establish procedures to verify that the system is working properly, and (vii) establish effective recordkeeping to document the HACCP system.

HACCP is implemented as a team exercise (14). The team is responsible for developing the initial plan and coordinating its implementation (13). The team consists of members who can confidently and easily identify hazards, CCPs, and critical limits associated with the food product and processes under consideration (4). Expertise in the processes and process control points is essential for a successful HACCP plan (18).

Systematic steps for creating a HACCP plan were introduced by Alvarez *et al.* (14) and are summarized in Table 1.

Conduct a hazard analysis

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) currently defines a hazard as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (13). The consideration of the likelihood of the hazard occurrence is usually based on a combination of experience, epidemio-logical data, and information in the technical literature (4). The objectives in the hazard analysis are to (i) identify hazards that are likely to cause injury or illness if not effectively controlled, (ii) identify control measures for identified hazards; and (iii) provide a basis for determining critical control points in the HACCP plan (2, 4).

Microbial hazards are the main concern in aseptic food processing. Microbial hazards may be identified in raw materials, processing equipment, and packaging systems (13). Cross-contamination of processed food during

Table 1. Steps in creating a HACCP plan

Step number	Plan description
1	Form a HACCP team.
2	Create and verify the process flow diagram (Fig. 1).
3	Add each Process Step from the process flow diagram (Fig. 1) onto the Hazard Analysis and CCP form (Table 2).
4	Complete the Hazard Analysis and CCP form for each Process Step and each Potential Hazard (biological, chemical, and physical).
5	Enter the Process Step/CCP on the Critical Limits, Monitoring, and Corrective Actions form (Table 3) for each Process Step/CCP identified from the Hazard Analysis and CCP.
6	Enter values on the Critical Limits, Monitoring, and Corrective Actions form for each critical limit.
7	Enter the Corrective Actions on the Critical Limits, Monitoring, and Corrective Actions for each Critical Limit.
8	Enter the Process Step on the Verification and Record Keeping form (Table 4) for each Process Step identified from the Hazard Analysis and CCP form (Table 2).
9	Enter all the Record-Keeping Procedures on the Verification and Record Keeping form for each Process Step/CPP.
10	Enter information listed on the HACCP Plan Summary (Table 5) for each Process Step/CCP identified from the Critical Limits, Monitoring, and Corrective Action form (Table 3).
11	All forms are to be reviewed for correctness, signed, and dated.

packaging and improper handling of the processed food during storage can also result in microbial contamination (4). Food pathogens of concern in juice products include *E. coli* O157:H7, *Salmonella*, and *Cryptosporidium*. Identified sources of pathogens include water, soil, fruits, processing under unsanitary conditions, airborne microorganisms in the storage area, infected workers, and food handlers (4). Some pathogens have adapted to the acidic environment of fruit juices, making juices susceptible to microbial contamination and the subsequent survival of the pathogens in juice products (4). Food-borne illnesses associated with microbiological activity may not become evident for some time. Tracking the contaminant can be difficult because of the time required for positive microbiological testing and confirmation (5).

Chemical hazards include tin, lead, and copper from pipe fittings on processing equipment, allergy-causing food ingredients such as FD&C Yellow No. 5, antibiotics, pesticides, cleaning detergents or sanitizer solutions, contaminants in packaging materials, botanical plant materials, and contaminated fruit (e.g., patulin in apples). Chemical hazards must be prevented in the first instance (4, 14). Unlike microbial contaminants, chemical contaminants cannot be destroyed or easily removed from contaminated foods. Chronic effects of chemical contaminants are difficult to assess because long-term monitoring of the health of individuals is impractical. Examples of chemical hazards involved in aseptically processed juice include antibiotics, pesticide residues, sterilizing agents such as hydrogen peroxide, and detergents used during CIP operations such as sodium hydroxide, nitric acid, and phosphoric acid (4, 18).

Physical hazards include foreign matter in raw materials such as soil, stones, glass, rubber, bolts, nuts, metal shavings, plastic pieces, and fragments of other packaging materials. Any debris from a damaged plastic or rubber seal is also considered a hazard (4, 18). The FDA's recall data indicate that physical hazards frequently cause companies to recall juice products (4).

Hazard analysis may begin with a current flow chart of the production process. A flow chart representing aseptic thermal processing for an orange juice drink is illustrated in Fig. 1. The source of ingredients, distribution, and marketing of the product can be shown in the flow chart (6). The HACCP team reviews the ingredients used in the product, all the activities conducted at each step in the process, the equipment used, the final product, the methods of storage and distribution, and the intended use by consumers of the product. Based on this review, the HACCP team develops a list of potential biological, chemical, or physical food hazards (4).

The hazard analysis consists of asking a series of questions to assist in identifying potential hazards (3, 4, 7). Examples of questions used to identify potential hazards in aseptic thermal juice processing are:

1. Does the juice contain any sensitive ingredients that may present microbiological hazards (e.g., *L. monocytogenes*, *Salmonella*, *E. coli* O157:H7), chemical hazards (e.g., pesticide residues), or physical hazards (e.g., metal, glass)?
2. What is the normal microbial content of the juice product?
3. Does the product permit survival or multiplication of pathogens and toxin formation in the product during processing?
4. Does the microbial population change during normal storage time of the product prior to consumption?
5. Does the subsequent change in microbial population alter the safety of the product?
6. Does the equipment provide controls for temperature and time of the desired thermal treatment?
7. Are the processing units properly sized for the volume of food that is subjected to the process?
8. Does the method of packaging affect the growth of microbial pathogens and the formation of toxins?
9. Does the package carry information and instructions for the safe handling and preparation of the product by the end user?

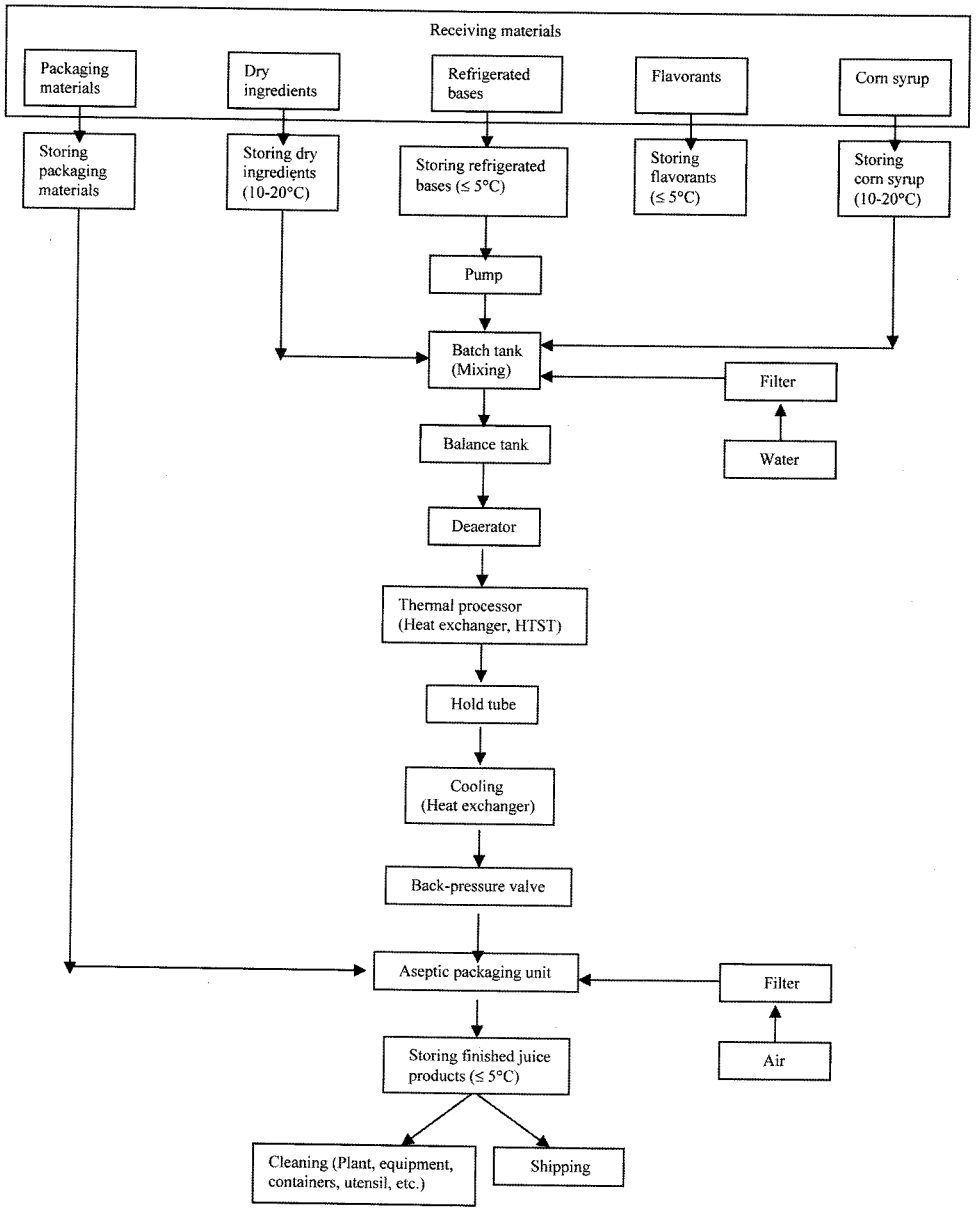

Fig. 1. A flow chart representing the aseptic thermal processing of a 10% orange juice drink.

10. Is the selected packaging material damage resistant?
11. Is the package labeling-friendly?
12. Does each package contain the proper label?
13. Is positive air pressure maintained in product packaging areas?
14. Which biological, chemical, or physical hazards are likely to occur if the product is subject to recontamination between processing and packaging?
15. Are the processing units designed so that they can be easily cleaned, sanitized, or sterilized?
16. Is the traffic pattern of people and moving equipment a source of contamination?
17. What hazard may result if the juice composition is not controlled?
18. What hazards have been associated with the product in the market place?
19. Can employee health or personal hygiene practices impact the safety of the product being processed?
20. Will there likely be leftovers?
21. Who is the intended consumer?

An example of the hazard analysis for the aseptic thermal processing of a 10% orange juice drink is presented in Table 2. The main causes of microbial contamination include: (i) poor hygiene of the personnel, (ii) inadequate cleaning procedures, and (iii) cross-contamination. Effectiveness of juice pasteurization or sterilization depends on the initial microorganism load and the growth rate of the microorganisms, the thermal processing parameters used, and the juice characteristics (e.g., pH, particles).

After a list of potential hazards is determined, each

Table 2. Hazard analysis and critical control points (CCPs)

Ingredient/ Process step	Potential hazards, introduced, controlled, or enhanced at this step[1)]	Is this hazard likely to occur?	Why? (Justification for decision made in previous column)	What measures can be applied to prevent, eliminate, or reduce the hazards being addressed in HACCP plan?	Is this step a CCP?
Receiving packaging material	B	Yes	Yes	Microbial contamination on the surface of packaging materials	Hydrogen peroxide (H_2O_2) sterilization. Maintenance of critical control records and personnel practices.	No
	C	No	No	Package has food grade contact surface	Specifications from supplier	No
	P	No	No	Package integrity failure, prerequisite program	Specifications from supplier	No
Receiving dry ingredients	B	Yes	Yes	Microbial contamination	Thermal sterilization	No
	C	No	No	Dry ingredients are FDA approved substances	Specifications from supplier	No
	P	No	No	Prerequisite program	Specifications from supplier	No
Receiving refrigerated bases	B	Yes	Yes	Microbial contamination	Temperature at receipt, thermal sterilization	Yes
	C	No	No	The bases have FDA approved substances	Specifications from supplier	No
	P	No	No	Prerequisite program	Specifications from supplier	No
Receiving flavorants	B	Yes	Yes	Microbial contamination	Thermal sterilization	Yes
	C	No	No	The flavorants are FDA approved substances	Specifications from supplier	No
	P	No	No	Prerequisite program	Specifications from supplier	No
Receiving corn syrup	B	Yes	Yes	Microbial contamination	Thermal sterilization	No
	C	No	No	The corn syrup is an FDA approved substance	Specifications from supplier	No
	P	No	No	Prerequisite program	Specifications from supplier	No
Storing packaging material	B	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Maintaining storage area according to prerequisite program	No
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
Storing dry ingredients	B	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Maintaining storage area according to prerequisite program	No
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	
Storing refrigerated bases	B	Yes	Yes	Controlled refrigeration is required for the quality and safety.	Storage temperature control, maintenance of critical control records and personnel practices	Yes
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No

Table 2. Continued

Ingredient/ Process step	Potential hazards, introduced, controlled, or enhanced at this step[1)]		Is this hazard likely to occur?	Why? (Justification for decision made in previous column)	What measures can be applied to prevent, eliminate, or reduce the hazards being addressed in HACCP plan?	Is this step a CCP?
Storing flavorants	B	Yes	Yes	Controlled refrigeration is required for the quality and safety	Storage temperature control, maintenance of critical control records and personnel practices	Yes
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
Storing corn syrup	B	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP)	Inspection under prerequisite program	No
Pump	B	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
Water	B	No	No	Prerequisite program (GMP)	Inspection under prerequisite program	No
	C	No	No	Prerequisite program-filtering	Inspection under prerequisite program	No
	P	No	No	Prerequisite program (GMP)	Inspection under prerequisite program	No
Batch tank (Mixing)	B	Yes	Yes	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	Yes
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
Balance tank	B	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
Deaerator	B	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
Thermal treatment/ Cooling (Heat exchanger)	B	Yes	Yes	The thermal treatment is the only step inhibiting microorganisms in the juice product for its microbiological shelf stability. Final thermal treatment time and temperature must be met.	Treatment time and temperature controls. Maintenance of critical control records and personnel practices	Yes
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No

Table 2. Continued

Ingredient/ Process step	Potential hazards, introduced, controlled, or enhanced at this step[1)]		Is this hazard likely to occur?	Why? (Justification for decision made in previous column)	What measures can be applied to prevent, eliminate, or reduce the hazards being addressed in HACCP plan?	Is this step a CCP?
Sterile air inlet	B	Yes	Yes	Air system is designed to deliver sterile air into the filler of the aseptic packaging unit to prevent microbial contamination using an appropriate filter	Inspection under prerequisite program. Maintenance of critical control records and personnel practices	Yes
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
Aseptic packaging unit	B	Yes	Yes	Aseptic packaging to prevent microbial contamination. (i) The unit sterilizes packaging materials (ii) Hydrogen peroxide must be dried by heating, not to be added to juice (iii) The filler sterility must be maintained	The sterilization and maintenance of the packaging material and filler are validated. Maintenance of critical control records and personnel practices	Yes
	C	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	No
	P	No	No	Prerequisite program-cleaning and maintenance programs (GMP, SSOP)	Inspection under prerequisite program	
Storing finished juice products	B	No	No	Prerequisite program-store area designated under GMP	Maintaining store area according to GMP in prerequisite program	No
	C	No	No	Prerequisite program-store area designated under GMP	Maintaining store area according to GMP in prerequisite program	No
	P	No	No	Prerequisite program-store area designated under GMP	Maintaining store area according to GMP in prerequisite program	No
Cleaning	B	No	No	Prerequisite program-cleaning practices in accordance to GMP, Cleaning-in-place (CIP) for thermal processor and the aseptic packaging unit	Maintaining plant, equipment, container, utensil, etc according to hygiene plans in prerequisite program	No
	C	No	No	Prerequisite program-cleaning practices in accordance to GMP	Cleaning according to chemical control and GMP in prerequisite program	No
	P	No	No	Prerequisite program-cleaning practices in accordance to GMP	Cleaning according to prerequisite program	No
Shipping	B	No	No	Prerequisite program-shipping practices in accordance to GMP	Maintaining shipping area according to GMP in prerequisite program	No
	C	No	No	Prerequisite program-shipping practices in accordance to GMP	Maintaining shipping area according to GMP in prerequisite program	No
	P	No	No	Prerequisite program-shipping practices in accordance to GMP	Maintaining shipping area according to GMP in prerequisite program	No

[1)] Hazards are classified as: B-biological, C-chemical, P-physical.

Approved by:_____ **Date:**_____

hazard is evaluated and sometimes graded based on the severity of the potential hazard and its likely occurrence (4, 13). Based on the hazard evaluation, potential hazards are selected and addressed in the HACCP plan. Control measures for the selected potential hazards are determined and also addressed in the plan. More than one control measure may be required for a specific hazard or more than one hazard may be addressed by a specific control measure (6, 13). A hazard analysis can be varied based on the type of juice products because different hazards may be associated with different products (4). A thorough hazard analysis is the key for an effective HACCP plan because the plan will not be effective regardless of how well it is followed if the hazards are not analyzed correctly.

Identify critical control points

A critical control point (CCP) is defined as any step where control can be applied that is essential to prevent or eliminate a hazard or reduce it to an acceptable level (1, 19). Complete and accurate identification of the CCP is fundamental to the success of the HACCP plan (4). The information gathered during hazard analysis enables the HACCP team to identify which steps in the process are CCPs (13). Each CCP can have one or more control measures.

The key criteria for the assignment of CCPs are (3, 4, 14):

1. At which point could the identified hazard occur at an unacceptable level?
2. Do preventative measures exist for the identified hazard? If a step contains no mechanism for the control of an identified hazard then it cannot be a CCP.
3. Can the identified hazard be more effectively controlled using other stages of food production? This question is necessary to screen for unnecessary CCPs.
4. Do we have to design a step to control the identified hazard?

A decision tree is often employed as a means of identifying CCPs (19). The CCPs identified in producing a 10% orange juice drink are listed in Table 2. It is the processor's decision whether or not the first CCP in its HACCP system is at the point of receipt of raw materials (6, 15).

Different facilities preparing the same food can differ in CCPs due to variations in equipment layout, selection of ingredients, and processes employed (6). For example, if an emerging technology such as pulsed electric fields (PEF) and high pressure processing (HPP) replace a conventional thermal treatment for juice production, classical quality control methods are inadequate to control hazards caused by these technologies.

The FDA proposed that juice processes achieve a 5-log reduction in microbial counts for the most resistant microorganism of public health concern that is likely to occur in the juice based on safety considerations and on the recommendation of the NACMCF (4). The processes include PEF and HPP as well as any conventional thermal pasteurization technologies. The NACMCF recommended the use of *E. coli* O157:H7 or *L. monocytogenes* as the target organisms, based on the number of known outbreaks of *E. coli* O157:H7 in juice and the ubiquitous nature of *L. monocytogenes* (4). The FDA has concluded that target pathogens must be chosen on the basis of historical association with a product and the way in which the product is processed (20). Un-pasteurized or un-sterilized juices must have a warning label, which must be visible on the information panel or on the principal display panel of the container's label and must read: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems" (4).

Processed juice should be packaged immediately to reduce the risk of recontamination after application of the 5-log pathogen reduction treatment (1). Processors not packaging juice immediately after treatment should have sufficient controls in place (e.g., aseptic equipment) to ensure that the safety achieved by the 5-log reduction can be consistently maintained (14). Integrity of food packaging must be assured because food products can become undesirable and unsafe to consumers if packaging fails (14). Food packaging materials should not transfer toxic substances to food and must be durable enough to remain intact during all subsequent packaging, transporting, storing, and retail operations (15).

Establish critical limits

When all CCPs are identified, their critical limits should be set up. The critical limit is defined as the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a CCP to prevent, eliminate, or reduce the identified hazard to an acceptable level (1). To determine the critical limits, standard guidelines are generally used, which have been developed by many regulatory agencies, such as the FDA, the U.S. Department of Agriculture, state inspection services, local departments of health, and industry associations (1, 6, 21). The process critical limits should be thoroughly reviewed and accepted by a qualified person(s) who has expert knowledge acquired through appropriate training and experience as indicated in the Code of Food Regulations, Title 21 (10).

The level of pasteurization or sterilization of juice products is dependent on processing parameters (e.g., treatment time and temperature), product parameter (e.g., pH, water activity, viscosity), and the characteristics of target microorganisms. The product viscosity affects residence time through the hold tube and treatment temperature. Products containing particles must be ensured for their thermal treatment on the center of the particles. If the critical limits of aseptic juice processing are not met during pre-sterilization, then the juice processing system should not advance to the next product treatment (e.g., sterilization) mode (10). If the critical limits are not continuously met during the transition from presterilization to product treatment or during a product treatment, the process water or product should automatically be diverted and the aseptic processing system should advance to a non-sterile mode (10). If the critical limits for the aseptic packaging unit, including the filter system, are not met during pre-sterilization, a sterilization step prior to filling, or a product filling step, then the aseptic packaging unit should not advance to a machine filling mode (10).

The critical limit of each CCP in the aseptic processing of a juice drink is shown in Table 3. The critical limits for the packaging unit can be further determined with pre-sterilization and sterilization conditions, the concentration and volume of a sterilizing agent, and pressures in the product filling system and sterile zone (10).

Establish monitoring procedures

Monitoring is a planned sequence of measurements to check if CCPs are under control and to keep an accurate record for future use in verification (1). It determines if a loss of control or a deviation has occured and, if so, when it happened. This monitoring provides accurate records for future use in verification (7, 22).

The choice of relevant measurement techniques is important. Many procedures are destructive and most employ solvents and materials that would render foodstuffs unsuitable for consumption. The microbial detection strategy relying on culturing microorganisms is cumbersome, time-consuming, and laborious, and thus is seldom an effective means of monitoring CCPs (23). For this reason, monitoring of CCPs can best be accomplished through the use of physical and chemical tests, and through visual observations (21). For example, the microbial safety of juice can be monitored based on thermal treatment conditions rather than performing microbial tests (21). The ideal way is to monitor deviations on-line to enable corrective action taken by a direct feedback procedure. The on-line monitoring test requires the development of rapid, robust, economical, and user-friendly analytical methods that are adopted to meet the criteria needed at the control points (19, 22, 23). A surface plasmon resonance (SPR) biosensor is an example of equipment that has been developed for on-line monitoring (23, 24).

Monitoring responsibility needs to be assigned for each CCP. Those assigned individuals must be trained in the purpose and importance of monitoring, monitoring techniques, and reporting procedures, especially for the case when a process or product that does not meet critical limits is found (1, 10, 18). The monitoring procedure for each CCP in the aseptic processing of a juice drink is proposed in Table 3.

Establish corrective actions

The corrective action is defined as procedures to be followed when a deviation occurs at a CCP (10). The corrective actions should: (i) correct the cause of non-compliance to prevent a re-occurrence, (ii) demonstrate that the CCPs are again under control, (iii) record and maintain the corrective actions that have been taken, (iv) determine the disposition of non-complying products, and (v) ensure that no products that are injurious to health are distributed for human consump-tion (18, 19). It should record specifically what is done, when a deviation occurs, and who is responsible for implementing the corrective actions. An individual who has a thorough understanding of the process, product, and HACCP plan should be assigned as the person responsible for corrective actions (4). Examples of corrective actions for each CCP in an aseptic juice processing are introduced in Table 3.

Establish verification procedures

Verification is categorized by (i) validation, (ii) verification, and (iii) reassessment (14). Validation is the element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan will successfully control the identified hazards when properly implemented (10). Validations are made when significant product, process, or packaging changes occur and new hazards are recognized. A subsequent validation is also conducted to confirm that changes have been implemented correctly after a HACCP plan has been modified (4, 10). Validation of the HACCP plan may be done by any individual, including a third party, and the results should be publicized (4, 10).

Verification is defined as the activities that determine the validity of the HACCP plan, other than monitoring, and examine if the system is operating according to the HACCP plan (14). Verification procedures are required to (13, 14, 25):

1. Confirm the accuracy of the flow diagram.
2. Review or validate the critical limits of the CCPs to ensure if they are satisfactory.
3. Confirm if the facility is operating according to the HACCP plan.
4. Review the records for CCP monitoring, deviations, and corrective actions.
5. Review the modifications of the plan.
6. Test to verify CCPs.
7. Confirm compliance of the HACCP system with government regulations.
8. Consider any consumer complaints about the food products.

A comprehensive verification must be periodically conducted by an unbiased authority (e.g., technical experts within a company and from regulatory agencies and a third party) (26). This verification must be performed to ensure that the HACCP plan is controlling all the identified hazards. If the results of the comprehensive verification identify deficiencies, the HACCP team modifies the HACCP plan as necessary (3).

Verification activities for each CCP in the aseptic processing of a juice drink are proposed in Table 4. For sterilization of a juice processor, hot water temperature and its residence time in the heat exchanger must always be equal or above the minimum specified limits in the heat exchanger. Juice residence time through the hold tube and temperature at the exit of the hold tube must be always equal or above the minimum limits for the juice process (pasteurization or sterilization). The temperature should be demonstrated with thermocouples or resistance temperature detectors (RTDs) at the furthest location from the heat exchangers (10). Sterile air or nitrogen is introduced into the filler bowl to maintain overpressure and prevent condensate after sterilizing is completed (10). Hydrogen peroxide residuals need to be assured by adequate drying to be sufficiently low before filling of juice begins (10). Hydrogen peroxide residuals in the container must meet the FDA requirements of 0.5 ppm or less for all filled containers (21 CFR 178.005) (10). The maintenance of the integrity of the sterile zone of the packaging unit may be demonstrated by pressure gauges and thermometers indicating pressures and temperatures inside the unit.

Table 3. Critical limits, monitoring, and corrective actions

Product: 10% orange juice drink						
Process step/CCP	**Critical limits[1)]**	**Monitoring procedures**				**Corrective actions**
		What	**How**	**Frequency**	**Who**	
Receiving refrigerated bases	Receipt temperature: ≤5°C	Temperature of product in package	Thermometer	Every incoming	Quality assurance (QA) technician	Reject shipped bases if the temperature is >5°C, record
Receiving flavorants	Receipt temperature: ≤5°C	Temperature of product in package	Thermometer	Every incoming	QA technician	Reject shipped flavorants if the temperature is >5°C, record
Storing refrigerated bases	Storage temperature: ≤5°C	Temperatures at room doorway and center of storage room	Continuous monitor with alarm when temperature rises above 5°C	Continuous	QA technician	Keep the material temperature at ≤5°C, terminate cause of alarm, reset and verify calibration against bulb thermometer reading, record maintenance
Storing flavorants	Storage temperature: ≤5°C	Temperatures at room doorway and center of storage room	Continuous monitor with alarmwhen temperature rises above 5°C	Continuous	QA technician	Keep the material temperature at ≤ 5°C, terminate cause of alarm, reset and verify calibration against bulb thermometer reading, record maintenance
Batch tank (Mixing)	pH <4.6	pH of mixed batch	Juice is sampled from the batch and pH is measured before thermal treatment	Every batch	Processor operator	Remix and retest until satisfactory value obtained, cause correction to prevent a recurrence, record maintenance
Thermal treatment/Cooling (Heat exchanger)	Temperature: 88°C, hold time 15 sec	Temperature: 88°C, hold time: 15 sec	Juice temperature in hold tube	Continuous	Processor operator	
Sterile air inlet	Air pressure: minimum 38 mbar	Sterile air pressure	Gauge on the filler of the aseptic packaging unit	At start of shift	Aseptic packaging unit operator	Feeding stops automatically when low flow alarm trips, disposition of non-complying product determined, cause correction to prevent a recurrence, record maintenance
Aseptic packaging unit	Steam sterilization, Hydrogen peroxide (H_2O_2) minimum dosage: 0.15 mL for 250 mL package, H_2O_2 heater minimum temperature: 130°C, H_2O_2 drying heater temperature: minimum 160°C	Temperature during steam sterilization, H_2O_2 drying heater temperature, H_2O_2 dosage indicator and H_2O_2 block heater temperature	Continuous monitor on gauges with alarm on the filler	Continuous	Aseptic packaging unit operator	Feeding stops automatically when low temperature alarm or H_2O_2 dosage alarm trips, disposition of non-complying product determined, cause correction to prevent a recurrence, record maintenance

[1)] Source of critical limit values: 21CFR114 and 178

Approved by: _____ **Date:** _____

Table 4. HACCP plan summary

Product: 10% orange juice drink						
Process step/CCP	**Hazard**	**Critical limit**	**Monitoring**	**Corrective action**	**Verification**	**Record keeping**
Receiving refrigerated bases	Biological	Receipt temperature: ≤5°C	Temperature of product in package every incoming shipment	Reject shipped bases if the temperature is >5°C, record	Recording temperature every batch, thermometer calibration, specifications of received materials, personnel trained, receiving area clean	Temperature records, calibration log, and specifications of received materials in a quality assurance (QA) lab file
Receiving flavorants	Biological	Receipt temperature: ≤5°C	Temperature of product in package every incoming shipment	Reject shipped flavorants if the temperature is >5°C, record	Recording temperature every batch, thermometer calibration, specifications of received materials, personnel trained, receiving area clean	Temperature records, calibration log, and specifications of received materials in a quality assurance (QA) lab file
Storing refrigerated bases	Biological	Storage temperature: ≤5°C	Continuous monitoring of temperatures at room doorway and center of storage room	Keep the material temperature at ≤5°C, terminate cause of alarm, reset and verify calibration against bulb thermometer reading, record maintenance	Checking and calibrating thermometer and alarm, personnel trained, storage area clean	Records in a maintenance office and calibration log in QA lab file
Storing flavorants	Biological	Storage temperature: ≤5°C	Continuous monitoring of temperatures at room doorway and center of storage room	Keep the material temperature at ≤5°C, terminate cause of alarm, reset and verify calibration against bulb thermometer reading, record maintenance	Checking and calibrating thermometer and alarm, personnel trained, storage area clean	Records in a maintenance office and calibration log in QA lab file
Batch tank (Mixing)	Biological	pH <4.6	pH of mixed batch	Remix and retest until satisfactory value obtained, cause correction to prevent a recurrence, record maintenance	Batch tank clean, recording pH, personnel trained	
Thermal treatment/Cooling (Heat exchanger)	Biological	Temperature: 88°C, hold time: 15 sec	Temperature: 88 °C hold for 15 sec verified by continuous monitoring	Juice not meeting the limits is automatically rejected or transferred to balance tank for reprocessing, readjust thermal treatment conditions including juice flow rate, record maintenance	Visual inspection, strip chart verification, strip chart recorder calibration for accuracy, personnel trained	Signed and dated strip charts and service records on file in QA lab
Sterile air inlet	Biological	Air pressure: minimum 38 mbar	Sterile air pressure checked at start of shift	Feeding stops automatically when low flow alarm trips, disposition of non-complying product determined, cause correction to prevent a recurrence, record maintenance	Filter maintenance, personnel trained	Maintenance record in QA lab file
Aseptic packaging unit	Biological	Steam sterilization, Hydrogen peroxide (H_2O_2) minimum dosage: 0.15 mL for 250 mL package, H_2O_2 heater minimum temperature: 130°C, H_2O_2 drying heater temperature: minimum 160°C	Temperature during steam sterilization, H_2O_2 drying heater temperature, H_2O_2 dosage indicator and H_2O_2 block heater temperature	Feeding stops automatically when low temperature alarm or H_2O_2 dosage alarm trips, disposition of non-complying product determined, cause correction to prevent a recurrence, record maintenance	Maintenance and calibration of thermometers (and RTD) and H_2O_2 dosage indicator for accuracy, personnel trained	Calibration in a field technician reports

Approved by: _____ **Date:** _____

Monitoring equipment must be carefully calibrated for accuracy. Verification reports may include certification that monitoring equipments are properly calibrated (1). Examples of monitoring equipment are (10):

1. Receiving and storing refrigerated bases and flavorants: Thermometers and RTDs.
2. Batch mix tank: pH meter.
3. Heating (high temperature short time)/cooling down: Flow meters, flow diversion valve, strip chart recorder, thermocouples and thermometers, RTDs.
4. Filler: Drying station heaters, peroxide dosage meter, peroxide dosage alarm.
5. Sterile air supply: Air pressure gauge, low flow alarm.

The occurrence of regular or preventable control losses indicates a need for the reassessment of the HACCP plan, which allows the changes or modification of HACCP in the production environment (25). An aseptic system should be reassessed when potential new hazards occur and anything that could affect the hazard analysis changes, which includes process, formulation, personnel, packaging, and finished product distribution. The reassessment must be done at least annually (1). A qualified person with expert knowledge must review and accept the reassessments.

Establish record-keeping procedures

Good HACCP records are important because (13):

1. Records serve as written documentation of the establishment's compliance with its HACCP plan.
2. Records allow the retail facility to trace the history of an ingredient.
3. Records help identify the trends in a particular operation that could result in a deviation if not corrected.
4. Well-maintained records can be used as evidence in potential legal actions against an establishment.

Record keeping should cover all the processing steps, from receipt of raw materials to distribution of finished products. The followings are examples of what should be included in the record (3, 14):

1. The list of the HACCP team and assigned responsibilities.
2. Description of food products, their intended use, distribution, and consumers.
3. Verified flow diagram of entire manufacturing processes.
4. Records of raw materials and packages.
5. Food material supplier certification records.
6. A summary of the hazard analysis and control measures.
7. Processing, storage, and distribution records including:
   a. Records indicating compliance with critical limits when packaging materials, labeling, or sealing specifications are necessary for food safety.
   b. Storage records.
   c. Monitoring records.
8. Deviation and corrective action records.
9. Verification records.
10. A HACCP plan summary.
11. Employee training records that are pertinent to CCPs and the HACCP plan.
12. Setup and maintenance manuals for equipment.
13. Operating instructions.

The FDA has concluded that records dealing with the HACCP plan must remain on site for at least 6 months. After that period, the records may be stored off-site if they can be retrieved and returned on-site to the plant within 24 hours so that plant managers and FDA investigators can readily access the records to evaluate the effectiveness of the HACCP plan (26).

A summary of the HACCP plan for the aseptic production of a 10% orange juice drink is shown in Table 4.

Conclusions

HACCP is widely accepted to be the most effective means of ensuring the safety of foods throughout food processing chain. Thus, it has been incorporated into food safety legislation worldwide and the need for HACCP is further increasing because of the growing trend in international trade for worldwide uniformity of food products. Education and training are very important elements of the HACCP concept. Employees who will be responsible for the HACCP program must be trained adequately in the principles, application, and implementation of the program. Once the HACCP system is developed, commitment to its proper implementation is crucial. With the increased demand for novel food processing technologies and international trade, HACCP must continue to be relevant and effective.

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