

The Role of Prerequisite Programs in Managing a HACCP System

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SUMMARY

Sound prerequisite programs are essential to successful development and implementation of a HACCP plan. In addition to those related to the GMPs, prerequisite programs can include systems such as ingredient specifications, consumer complaint management, ingredient-to-product traceability programs, and supplier approval programs. Prerequisite programs are not part of the formal HACCP system. They frequently function across product lines and are often managed as facility-wide or company-wide programs rather than being product or process specific, as is the case with HACCP systems. Although occasional deviation from a prerequisite program requirement would not by itself be expected to create a food safety hazard or concern, prerequisite programs play an important role in controlling potential health hazards.

Prerequisite programs are not part of the formal HACCP system. They frequently function across product lines and are often managed as facility-wide or company-wide programs rather than being product or process specific, as is the case with HACCP systems. Prerequisite programs can include objectives other than food safety, and it may not be easy to associate performance of a prerequisite program element, e.g., pest control or chemical storage programs, with specific production lots or batches. Consequently, it is usually more effective to manage them within a quality system rather than including their performance and control as part of the HACCP plan. This is appropriate provided that uninterrupted adherence to the prerequisite program is not essential for food safety. Occasional deviation from a prerequisite program requirement would not by itself be expected to create a food safety hazard or concern.

Nevertheless, prerequisite programs play an important role in controlling potential health hazards. For example, supplier control programs and chemical control programs can be used to minimize potential chronic health hazards such as those from mycotoxins or pesticides. Similarly, foreign material contamination in many food processes can be minimized by

INTRODUCTION

Since the first use of HACCP in American food plants over twenty-five years ago, it has been learned that HACCP cannot be successfully applied in a vacuum. Rather, HACCP must be supported by a strong foundation of prerequisite programs (15). It cannot be overemphasized that sound prerequisite programs are essential to successful development and implementation of a HACCP system.

Food processors in the United States recognize that many of the prerequisite programs are based upon the current Good Manufacturing Practices (GMPs) listed in the Code of Federal Regulations (8). In addition to those related to the GMPs, prerequisite programs can include other systems such as ingredient specifications, consumer complaint management, ingredient-to-product traceability programs, and supplier approval programs.

TABLE 1. Summary of prerequisite program activities**FACILITIES**

Adjacent properties
 Building exterior
 Building interior
 Traffic flow patterns
 Ventilation
 Waste disposal
 Sanitary facilities/handwashing
 Water, ice, culinary steam
 Lighting

RAW MATERIALS CONTROLS

Specifications
 Supplier approval
 Receipt and storage
 Testing

SANITATION

Master schedule
 Pest control
 Environmental surveillance
 Chemical control

TRAINING

Personal safety
 Personnel GMPs
 HACCP

PRODUCTION EQUIPMENT

Sanitary design/installation
 Cleaning/sanitation
 Preventive maintenance
 Calibration

PRODUCTION CONTROLS

Product zone controls
 Foreign material control
 Metal protection program
 Allergen control
 Glass control

STORAGE & DISTRIBUTION

Temperature control
 Transport vehicle cleaning
 & inspection

PRODUCT CONTROLS

Labeling
 Product trace
 Complaint investigations

tation of consistent performance of the prerequisite programs. If a prerequisite program is not conducted adequately, then the hazard analysis may be in error, and the HACCP plan may be inadequate. If the HACCP team cannot depend on consistent control of the prerequisite program, then additional CCPs may need to be added to the HACCP plan, increasing the plan's complexity. In short, reliance on well developed and consistently performed prerequisite programs can simplify the HACCP plan. Reliance on poorly developed or performed prerequisite programs can be detrimental to food safety. Therefore, in the interest of food quality, food safety, and regulatory compliance, it is imperative that all food processors establish, document, and maintain effective prerequisite programs to support their HACCP systems.

PREREQUISITE PROGRAMS

Many activities can be considered part of a prerequisite program. For this reason, it is quite likely that no two companies or plants will have identical prerequisite programs (Table 1). In this paper we have organized the many potential prerequisite activities into eight main areas. Depending on individual preference, either the individual activities or even the main areas could be rearranged to suit a given plant's prerequisite program needs. The information below is meant only to introduce basic information; for details, consult the references provided.

Facilities

Sanitary design principles should be observed in the planning, construction, and maintenance of all facilities (13).

Adjacent properties

Plants should be located so that contamination by microbes or chemicals from adjacent properties is unlikely. Typical properties to be avoided would include facilities that

preventive maintenance programs and by upstream control devices such as sifters or magnets.

Deviations from compliance with a prerequisite program usually do not result in action against the product. In contrast, potential acute health hazards such as the presence of *Salmonella* are usually controlled in a HACCP system where, in most cases, definitive Critical Control Points to eliminate the hazard are available. Deviations from compliance in a HACCP system normally result in action against the product, such as evaluation of product to determine appropriate action. This is a key consideration that can aid in distinguishing between control points within prerequisite programs and critical control points that should be covered by a HACCP plan.

Regulatory agencies in North America have recognized the importance of prerequisite programs and have incorporated them into regula-

tory programs and new regulations. The Canadian Food Inspection Agency includes prerequisite programs in its Food Safety Enhancement Program (1). In the United States, similar inclusions were made in new HACCP regulations for seafood processing (6) and meat and poultry processing (11).

In 1995, the U.S. Food and Drug Administration (FDA) began a pilot program in collaboration with the U.S. food industry to study the use of HACCP systems in many types of food processing operations (7). Industry participants reported that FDA focused a great deal of attention on the existence and maintenance of prerequisite programs (Sperber, personal communication; 7).

Prerequisite programs are the foundation upon which the HACCP plan is built (15). In the hazard analysis, the likelihood of hazards occurring is assessed with an expect-

manufacture noxious chemicals, animal feed lots, and waste disposal areas.

Building exterior

All grounds and roads should have adequate drainage. Grounds should be paved to minimize dust. There should be no vegetation immediately adjacent to buildings. All debris and garbage should be contained.

Building interior

The building should be designed to prevent pest entry. It should have the necessary sanitary design features to facilitate cleaning.

Traffic flow patterns

A linear product flow should be established so that raw materials are received at one end of the plant and finished products are shipped from the opposite end. Where necessary, workers, equipment and hand tools should be restricted to either raw or finished product areas so that the possibility of cross-contamination is minimized.

Ventilation (18)

Intake air should be filtered. Air intakes should be on the roof or at least six feet above the ground. They should not be able to pick up dust, noxious odors, or exhaust air from the plant. Positive air pressure should be maintained in finished product areas to prevent contamination from exterior or raw material handling areas.

Waste disposal and waste management (14)

The plant should have proper sanitary sewers. Waste containment and removal procedures should be in place.

Sanitary facilities and hand washing

The plant should have adequate washroom facilities for each gender. The washrooms must not enter directly onto the production area. Handwash stations should be available so that employees can wash their

hands before entering the production area. Handwash stations can also be conveniently located throughout the production area. Each station must have potable hot and cold running water, hand soap, and hand sanitizer. Preferably, the faucets should be foot or electric eye operated. Hands should be dried with single-use disposable towels or hot air dryers.

Water, ice, and culinary steam (14, 18)

Potable water should be used in most applications. Water testing records must be maintained. Water should be chlorinated. Adequate controls and documentation must be in place when in-plant chlorination systems are used. There must be no cross-connections between potable and non-potable water lines. Only approved boiler compounds can be used in the generation of culinary steam (9, 18).

Lighting

Lighting should be adequate to carry out plant operations and protected so that broken glass will not be a potential hazard.

TRAINING

Training may be done by outside organizations but more frequently will be done in-house. Training materials may include videos and interactive CD-ROMs. The training must be documented and a record should be included in the employee's personnel file. Periodic refresher training should be part of the overall training program.

Personal safety

Written procedures should be in place so that all employees can be trained in the safe operation of the equipment with which they work. All employees should understand what initial actions to take should an accident occur.

Personnel GMPs (18)

Employees should receive documented training in the plant's procedures to assure personal hygiene. Procedures will include hand

washing, hair containment, and appropriate clothing and shoes. Employees must not wear jewelry or eat, drink or smoke in production areas. Employees who are sick or have a disease that is transmissible via food may not handle food or work in a food production area.

HACCP

All employees must receive documented training in the plant's HACCP system. At individual work stations the employees must be aware of the hazard(s) being controlled, the location of critical control points, the critical limits to be met, the monitoring procedures used, records to be kept, and the corrective actions to be initiated should a deviation occur. The employee should also be made aware of the potential consequences to consumers if a failure occurs.

RAW MATERIAL CONTROLS

Specifications

Written specifications should be in place for all chemicals, pesticides, food ingredients and packaging materials. The specification should include product description; transportation and storage requirements; required analytical tests, etc.

Supplier approval or certification

All suppliers should be approved for compliance with GMPs, HACCP, etc., and for the ability to produce the specified material. Auditing a supplier's control programs (HACCP plan, prerequisite programs) is the best means of approving suppliers and assuring compliance. Some end-product testing may be appropriate as a verification of the control program. In such cases, suppliers may be certified to perform end-product testing to minimize the need for testing at the receiving plant. A Certificate of Analysis (COA) will suffice in this instance. This can be an important tool for management of ingredients that may contain hazards. However, it must be recognized that end-product testing is a

very poor means of assuring the absence of a hazard, especially for hazards expected to be present at low levels or absent.

Receipt and storage

The raw material receipt and storage area should be separate from the processing area and ideally will also be separate from the shipping area. The receipt and storage area must be maintained in sanitary condition. In some cases, raw materials should be quarantined until the required tests are completed with satisfactory results. The materials can then be released to production. Raw materials should be stored at the appropriate temperature and relative humidity and kept separate from finished products.

Testing procedures

Each raw material should be subjected to an acceptance test. The tests may be subjective organoleptic tests for visual or odor characteristics. In some cases specific tests, e. g., *Salmonella* testing, may be necessary to verify the effectiveness of the supplier's HACCP and quality programs. Generally these tests are random rather than routine.

PRODUCTION EQUIPMENT

Sanitary design and installation

Sanitary design principles should be used in the design and manufacture of food production equipment (13). The equipment should be designed to prevent the contamination of food or the growth of microorganisms during production. All lubricants must be food grade (10); the supplier should be able to provide verification that lubricants are food grade.

Cleaning and sanitation

Written procedures should be in place for the cleaning and sanitation of all food processing equipment. The proper steps should be followed for the use of detergents and sanitizers (14, 18). Separate color-coded utensils should be used for raw and cooked food equipment.

Preventive maintenance

A predetermined schedule for the servicing of all equipment should be in place. Preventive maintenance can be key in ensuring that equipment functions properly during production. Maintenance procedures should specify checks to ensure that no extraneous parts or maintenance tools or materials are left behind to contaminate products.

Calibration

Equipment should be calibrated as necessary. Generally, a schedule for calibration will be established based upon manufacturers' recommendations or upon experience. Equipment to be calibrated includes various types of thermometers or thermocouples, pH meters, and relative humidity sensors. The standard or reference used in calibration must be documented for traceability. Calibration is particularly important for instrumentation used to monitor critical control points. In this case, the calibration process may be considered part of the HACCP verification step.

SANITATION

Master sanitation schedule

A master sanitation schedule should be developed and rigorously applied to assure good housekeeping and minimize product exposure to contamination. This schedule applies to floors, walls, ceilings, lights, overheads, and all other areas that are cleaned on a less-than-daily frequency. A control program for storage and use of cleaning and sanitation chemicals should be included.

Pest control (14, 18)

All doors and windows should be adequately screened to exclude pests. The walls and roofs should have no other openings that would permit pest entry. Rodent bait stations and traps are typically used. Each is numbered and indicated on a map of all such devices. All bait stations should be checked at some frequency and the date each trap is checked should be documented. Poisoned bait is not

permitted inside the plant. All pesticides should be properly labeled and stored and should be used only by a certified pesticide applicator.

Environmental surveillance

The environmental surveillance program consists of monitoring for microbiological contamination to verify the effectiveness of the plant sanitation programs. Examples of such programs include monitoring for *Listeria* spp. in areas where cooked, refrigerated, perishable products are packaged; monitoring for *Salmonella* spp. in areas where dried dairy products are handled; and determination of total microbial counts as a general indication of sanitizer effectiveness. ATP bioluminescence methods are gaining acceptance as a means of rapidly identifying areas where sanitation has not been done effectively (3, 4, 5, 12).

Chemical control

All non-food chemicals must be properly labeled and stored in an area separate from food storage areas. The chemicals should be mixed, dispensed, and used only by properly trained personnel.

PRODUCTION CONTROLS

Many plants have in place quality management programs that can be used to manage production controls. Examples include Good Manufacturing Practices programs, ISO-9002, and statistical process control programs.

Product zone controls

All areas where products are handled must be maintained at the proper temperature. The control of employee and equipment traffic may be necessary to prevent the contamination of finished products. In some finished product packaging rooms, positive air pressure is necessary to minimize product contamination.

Foreign material control

Many devices such as sifters, screens, and filters can be used to detect or eliminate foreign material from a food process. These are usu-

ally located in production lines before critical control points.

Metal protection program

Magnets are a specific example of a foreign material control device. In some cases they may be managed as a critical control point. In other cases they can be located in the process before the final metal detector, in which case the magnets would be control points and the metal detector would serve as the critical control point, provided that metal contaminants in the product pose a significant health risk.

Allergen control

It is necessary to prevent cross contamination of allergenic materials to foods that do not contain the allergen. This is accomplished by rework control, production sequencing, equipment clean-outs between products, and strict attention to product labeling (2).

Glass control

An acceptable glass quality program is necessary to assure that the package can be adequately sealed and processed. It is also important to maintain a program that prevents or detects in glass containers glass fragments that could occur through manufacturing defects or through distribution. Electronic empty-glass-container inspection systems are available for 100% inspection of incoming glass for foreign glass and/or manufacturing defects. Glass containers are also typically washed prior to filling to remove any foreign debris from the package. In addition to these precautions, a rigid program is needed to manage glass breakage on the processing line, including inspecting the filling and capping line for breakage at set intervals.

STORAGE AND DISTRIBUTION

Temperature control

Where proper temperatures during storage and distribution are necessary for product quality and safety, temperatures must be monitored and documented. It is the

manufacturer's responsibility to establish the specific temperatures at which products must be transported and stored. In most cases, these temperatures are set to ensure the quality needed to meet consumer expectations and are much more stringent than needed for safety.

Transport vehicle cleaning and inspection (16)

Vehicles used for the transportation of food must be clean and sanitary. This is especially important in bulk transportation by truck, rail car, or ship. Proper cleaning and sanitation procedures must be followed and documented. Records of the prior three cargoes and the most recent cleaning of the conveyance should be available. The transportation equipment must be inspected and approved before loading.

PRODUCT CONTROLS

Labeling

It is essential to have the correct label on each package for compliance with food-labeling regulations and to reduce the risk of inadvertent allergens in foods (2).

Product trace, hold, and retrieval

Each plant must be able to trace all raw materials and finished products in order to conduct a product retrieval. A crisis response plan and a crisis response team should be in place to handle such incidents (17). Proper lot coding of all materials is necessary to limit the amount of material to be retrieved. Complete distribution records should be maintained so that the geographical extent of the retrieval is known. It is important to remove the implicated material from commerce as quickly as possible. Once retrieved, the manner of product disposition, e.g., rework or destruction, should be determined.

Complaint investigations

Consumer complaints should be reviewed carefully, because feedback from customers or consumers may identify problem areas that can

be corrected, leading to improved effectiveness of the affected prerequisite program.

IMPLEMENTATION AND VERIFICATION

There are several aspects to managing a prerequisite program: written Standard Operating Procedures, or SOPs; training; documentation; validation of the program's adequacy; and verification of compliance with the written program.

The existence and performance of prerequisite programs must be well documented. Prerequisite programs are established and managed separately from HACCP systems. However, the existence of a prerequisite program does not preclude the use of specific activities within a HACCP system. For example, while sanitation procedures are normally part of a prerequisite program, some manufacturers have chosen to manage selected sanitation procedures as CCPs in their HACCP systems. This has been done frequently in the meat and dairy industries, where sanitation procedures for meat slicers, ice cream fillers, etc., were established as CCPs to help prevent recontamination of cooked products by *Listeria monocytogenes*.

How a plant manages its prerequisite programs will have a direct impact on verification of the prerequisite programs. For example, if a plant manages its prerequisite programs as verbal practices, without regular documentation, then compliance will be very difficult to verify. If a plant manages its prerequisite programs systematically with written procedures, assigned responsibilities, measurable acceptance criteria, defined record keeping activities, and procedures to be followed when acceptance criteria are not met, then verification can also be systematic and performed in a more objective manner.

As with a HACCP plan, a well written prerequisite program clearly communicates what is expected to be performed and at what frequency,

who has responsibility, and what actions are to be taken if the activity is not performed according to procedure or does not have the expected outcome.

Management of a prerequisite program can be the responsibility of any of a number of departments. For example, responsibility for a plant's equipment calibration and preventive maintenance programs usually will reside with Maintenance or Engineering. Quality Assurance usually has responsibility for ingredient testing programs, hold and release programs, and recall systems, while Production has responsibility for sanitation programs and personnel hygienic practices.

For some programs, joint management may be most effective. For example, because control of raw materials relies on purchasing specifications and on inspection of materials upon receipt, a company may find it most effective for that program to be jointly managed by Purchasing, Quality Assurance, and Production. Purchasing sets up the initial procurement of the material according to a contract or agreement with the supplier. Quality Assurance, or Production inspects the material at receipt and takes appropriate actions (e.g., accepts or rejects material) based upon the specification. Quality Assurance or Production informs Purchasing of any out-of-specification material, and Purchasing takes appropriate action with the supplier.

Each SOP related to a prerequisite program should include procedures for routine verification. This activity, usually conducted by a supervisor, should verify that the SOP is being performed, monitored, and recorded in the manner intended. Periodically, the prerequisite programs must be independently audited, usually by Quality Assurance, to verify

and document that the overall program is being performed as intended. Outside auditors may also be used periodically.

Prerequisite programs are established and managed separately from HACCP systems. Because of the importance to HACCP, the satisfactory implementation of prerequisite programs must be verified. Reports of audits of prerequisite programs provide valuable information for the HACCP team to use in evaluating the nature and effectiveness of the individual prerequisite programs.

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REFERENCES

1. Canadian Food Inspection Agency (CFIA). 1998. Food Safety Enhancement Program. Volume 4, Operational Guidelines, 2nd edition, Appendix II CFIA, Ottawa, Canada.
2. Deibel, K., T. Trautman, T. DeBoom, W. H. Sveum, G. Dunaif, V. N. Scott, and D. T. Bernard. 1997. A comprehensive approach to reducing the risk of allergens in foods. *J. Food Prot.* 60:436-441.
3. Flickinger, B. 1996. Plant sanitation comes to light. *Food Qual.* 2 (June/July):22-36.
4. Flickinger, B. 1997. Light up your plant Part II. *Food Qual.* 3 (March): 20-22.
5. Flowers, R., L. Milo, E. Myers, and M. S. Curiale. 1997. An evaluation of five ATP bioluminescence systems. *Food Qual.* 3 (March):23-33.

6. Food and Drug Administration. 1995. Procedures for the safe and sanitary processing and importing of fish and fishery products; final rule. *Fed. Regist.* 60:65096-65202 (December 18).
7. Food and Drug Administration. 1996. HACCP pilot program. Interim report of observations and comments. FDA Center for Food Safety and Applied Nutrition. June 19. Washington, D.C.
8. Food and Drug Administration. 1997. Current good manufacturing practice in manufacturing, packing, or holding human food. Code of Federal Regulations No. 21, Part 110. U.S. Government Printing Office, Washington, D.C.
9. Food And Drug Administration. 1997. Boiler water additives. Code of Federal Regulations No. 21, Section 173.310. U.S. Government Printing Office, Washington, D.C.
10. Food and Drug Administration. 1997. Lubricants with incidental food contact. Code of Federal Regulations No. 21, Section 178.3570. U.S. Government Printing Office, Washington, D.C.
11. Food Safety and Inspection Service. 1996. Pathogen reduction; hazard analysis and critical control point (HACCP) systems. *Fed. Regist.* 61: 38806-38989 (July 25).
12. Griffiths, M. W. 1996. The role of bioluminescence in the food industry: new light on old problems. *Food Technol.* 50:(6):62-72.
13. Imholte, T. J. 1984. Engineering for food safety and sanitation. A guide to the sanitary design of food plants and food plant equipment. Technical Institute of Food Safety, Crystal, MN.
14. Katsuyama, A. M. (ed.) 1993. Principles of food processing sanitation. The Food Processors Institute, Washington, D.C.
15. National Advisory Committee on Microbiological Criteria for Foods. 1997. Hazard analysis and critical control point principles and application guidelines. Adopted August 14, 1997. FSIS, Washington, D.C.
16. National Food Processors Association. (undated). Tank truck inspection guidelines. NFPA, Washington, D.C.
17. National Food Processors Association. 1988. Manual on pre-emergency planning and disaster recovery. NFPA, Washington, D.C.
18. Troller, J. A. 1993. Sanitation in food processing. 2nd ed. Academic Press, Inc., New York.