

Effective HACCP Plan: Not Just a Fairytale

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A story in two acts in which your plant commits to quality improvement, then makes it happen. Everyone lives happily ever after.

The Players:

Plant Manager

President

HACCP Auditor

HACCP Systems Coordinator

ACT I: HACCP Prerequisites

by Debbie L. Newslow

You can't put the cart before the horse: Well-designed prerequisite programs provide a solid foundation for every effective HACCP plan.

Our story begins when a food company decides to identify and control potential hazards that are critical to consumer safety. The focus of HACCP is on product safety. HACCP should be a core part of your quality system. According to Ronald H. Schmidt, Professor of Food Science and Human Nutrition at the University of Florida, Gainesville, HACCP is a "logical system designed to identify hazards and/or critical situations and to produce a structured plan to control these situations." But a HACCP plan is not a stand-alone system. In assessing hazards, other related activities provide support to the HACCP plan. These are prerequisite programs. For instance, the GMP requirement of a company defines and controls the use of loose jewelry, hand washing, hair protection, use of glass in production areas, etc.

In its 1997 document titled "Hazard Analysis and Critical Control Point Principles and Application," the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) states, "The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs...Prerequisite programs provide the basic environment and operating conditions that are necessary for the production of safe, wholesome food."

The success of the HACCP system depends on prerequisite programs that are both active and effective. Many potential hazards can be eliminated or reduced to a "non-hazardous" state through well-defined and effective prerequisite programs.

NO EASY WAY OUT

So, why bother with the prerequisite program if HACCP can do the same thing? Creating critical control points (CCPs) and managing them through the HACCP plan is not always a viable option. CCPs have significant requirements. Introducing a CCP places demands on the system, which may not always be practical. Deviation is critical and must be addressed, documented and supported by records to demonstrate actions taken. A pre-determined corrective action must define an immediate action to divert the product and to ensure that violated product is not released for consumption. Whenever possible, the best solution is to define and manage as many potential hazards as possible in a prerequisite program.

The focus of prerequisite programs do differ from the overall HACCP focus. Generally, a prerequisite program applies across product lines that are managed system or process wide. The HACCP plan focus is product specific. Every deviation in a prerequisite program's requirement will not necessarily result in a food safety hazard, yet the effectiveness of the overall program may affect the HACCP system (product safety).

A LOOK AT POTENTIAL PREREQUISITE PROGRAMS

Prerequisite programs may be unique to each process. There really is no right or wrong program. Ideally, a cross-functional, trained team develops the HACCP plan. During this process, the team identifies potential hazards, and if possible, develops corresponding prerequisite programs that eliminate or reduces the hazard to a non-hazardous state.

Good Manufacturing Practices (GMPs) Including an operation's basic GMP program as a prerequisite program is common and makes good business sense. These requirements may be defined in one overall program or divided into subprograms, including:

- Building design and maintenance (interior and exterior, even weed control);
- Loose jewelry and hair constraints;
- Food hygiene, which may include the use, locations and maintenance of hand washing and sanitation facilities, including foot wash stations;
- Traffic control (to protect against cross contamination between associates working in raw material areas and cooked product areas);
- Adequate lighting and lighting protection;
- Foreign material control;
- Product storage and distribution including a first-in-first-out shelf life system; and
- Pest control.

GMP program requirements should be defined clearly and include an effective method (i.e., internal audit program) to monitor compliance and overall effectiveness.

Sanitation Programs These define requirements for cleaning and sanitizing activities. In some industries, such as juice processes, documenting these requirements in sanitation standard operating procedures (SSOPs) is required. Obligation or not, requirements for performing sanitation activities should be clearly defined in written procedures. Training must be performed in an effective manner that ensures responsible associates understand and perform all assigned tasks competently.

Foreign Material Control Foreign material may be controlled by filters, strainers, socks or sifters. Magnets are also considered a form of foreign material control. The prerequisite program determines placement and monitoring activities. In some operations, a unit strategically placed in the process may be identified as a CCP. Whether a CCP or managed as a prerequisite, monitoring requirements should be defined and records demonstrating compliance maintained.

Water Quality and Water Treatment Programs The internal requirements for ensuring the safety of the water supply will depend on its source. An effective chlorination process supported by records confirming acceptable water potability would be necessary for well water used in production whereas a certificate of compliance combined with periodic (i.e., quarterly, semi-annual) lab testing may be sufficient for city water. Keep in mind that ensuring the safety of the water supply may also include attention to boiler additives, ice production, and other water quality/treatment activities.

Quality Control and Microbiological Testing Depending on the operation, various quality control/quality assurance programs (i.e., microbiological testing, temperature monitoring, pH testing) may be included in prerequisite programs. In most instances, these programs verify and validate the HACCP plan. However incorporated into the plan, specific tests, frequencies and acceptable parameters must be identified and records maintained.

Document Control An effective document control process will include defined requirements for preparing procedures, work instructions, forms, and other instructional documents. It should also define requirements for revising and distributing documents. A master list of all documents that includes the current revision status of each document and its distribution must be maintained. This ensures all obsolete documents are retrieved and replaced with current versions. Distribution may include hard-copy versions (maintained in binders or posted in high-traffic areas) or accessibility through computer terminals. Having current requirements accessible where needed will prevent needless problems.

Pest Control Pest management may be included in the GMP program or exist as a stand-alone program. This depends on how responsibilities within the operation are assigned. If an external supplier provides these services, ensure that requirements are clearly communicated to the supplier and that records are maintained to confirm not only that activities are being performed as defined, but also that any identified pest control concerns are addressed in a timely and effective manner.

Calibration Any equipment used to demonstrate compliance to a specified requirement must be calibrated. Calibration confirms the accuracy of the equipment and should be measured against a known standard. A master list of equipment requiring calibration, frequencies, methods, tolerances, responsibilities, etc., should be maintained along with the required action if an instrument tests outside acceptable tolerances during routine calibration. Product tested (dating back to the last acceptable calibration check) with out-of-compliance equipment must be evaluated to ensure that it was indeed acceptable. If calibration is an element of the HACCP plan, prove that no food safety hazard was created. Deviations are addressed through programs that control nonconforming product or product recall.

Supplier Certification and On-going Evaluation Programs Supplier assurance that specific criteria are met should be an essential part of the HACCP plan. Many potential hazards related to the raw ingredient supply may be controlled through an effective supplier assurance program. Supplier programs should include requirements for identifying and qualifying suppliers, the means to monitor existing suppliers at defined frequencies, and handling any negative supplier issues. Keep in mind that if an assurance is made based on a COA (certificate of approval) or a COC (certificate of compliance) then the process should also identify a means to spot check incoming items (testing, etc.) at a defined frequency to verify the accuracy of the supplier's results.

Receiving, Storing and Controlling Raw Ingredients and Materials Inspections performed on raw ingredients and materials must ensure that all defined requirements are in compliance for the specific item before its receipt and are especially critical for requirements related to food safety hazard. Procedure requirements should be well defined; inspection and verification activities should be documented and maintained. Receiving inspection may link closely with supplier approval and evaluation requirements. All items must be stored in a manner that assures quality and protects their safety.

Product Identification, Traceability and Recall Programs The ability to identify and trace raw materials through finished product is essential. The product recall program should include mock recalls performed at a defined frequency (i.e., semi-annually) and records confirming acceptable results. Do not wait for a real situation to learn the program is not effective.

Labeling (Application and Control) Product must be labeled appropriately; labels must clearly identify the product and its ingredients. Labels must be evaluated to ensure that they contain all required information and meet legal requirements for product identification and content. Evaluation should be performed to ensure proper labels are applied to corresponding products. An ineffective label-management program could result in a serious food safety issue.

Allergen Control Depending on product, allergen control may be identified as a potential hazard. It is imperative that possible allergens and required controls specific to each manufactured product are identified. As appropriate, requirements to ensure that products are allergen free must be defined clearly with records maintained to confirm compliance.

Preventive Maintenance Successful operations perform preventive maintenance (PM) to ensure uninterrupted process; however, many do this informal-ly. A better approach is to formalize the procedures: Identify equipment, required maintenance, frequencies, etc., then document performance. Prioritize to identify critical equipment that must be maintained in a timely fashion, the neglect of which could jeopardize product safety, quality or overall production. A small company may use a structured inventory system instead of a formal PM program to ensure that there are always spare parts for the critical equipment. The system that works best is well defined.

Record Control HACCP's Principle Seven (see box below) requires an "effective record keeping system that documents the HACCP plan." Readily accessible records must provide evidence that CCPs have been established according to required procedures, and prerequisite programs are maintained in an effective manner. Without the proof (record), the activity is not technically complete. There can be no assumptions nor must any activity be left to interpretation. These record-control programs should include the identification of the records, retention times, responsibilities, requirements for completion, etc. These records should be completed in permanent ink; all changes to the document must be initialed. A strong argument can be made supporting a perception of data impermanence when pencil, erasers, and correction fluid are used.

Training Training is an essential HACCP requirement mentioned by the Codex Alimentarius Commission² that is not specifically stated as one of the seven principles. Codex states, "Training of personnel...in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP." It is imperative that associates are trained in their responsibilities. Qualification and competency requirements for specific responsibilities, including those related to the HACCP plan, must be defined with records maintained to confirm that requirements have been met. This must include personnel on temporary assignment, individuals filling in during breaks, vacations or sick leave, even those hired through a temporary agency. Well-defined and effective training cannot be stressed enough.

Prerequisite programs can include hazardous and chemical material control, sensory testing and training, control of nonconforming product, customer complaints and internal auditing.

Any discussion related to HACCP must emphasize management commitment. Though management commitment is not one of HACCP's seven principles, the Codex document states, "Management commitment is necessary for implementation of an effective HACCP system" and emphasizes that "the successful application of HACCP requires the full commitment and involvement of management and the work force." Management must convey a positive message of commitment through all levels of the operation in both words and actions. Management should conduct formalized meetings-perhaps quarterly-to evaluate the suitability and effectiveness of all HACCP-related activities. Any concerns or weaknesses in these should be addressed to ensure product safety.

Individual prerequisite programs and their role within a HACCP plan must be identified. These internal decisions must be based on a realistic evaluation of what is necessary to ensure product safety. Wherever possible, hazards should be addressed in a prerequisite program. This will strengthen the process overall, allowing an effective focus on CCPs and their relationship to the production of a safe product.

Keep in mind that a HACCP plan is not static; it requires periodic verification to confirm that all defined requirements are performed and validated, to confirm that the defined requirements are the correct requirements, and to ensure the production of a safe product. The role of prerequisite programs may change; every program should be continuously managed to be the best that it can be. Well-designed prerequisite programs provide a solid foundation for every effective HACCP plan. Remember there is nothing more important than to produce a safe product; product that each associate would feel safe to feed his family. Safety comes first.

REFERENCES

1 Schmidt, Ronald H., "Hazard Analysis and Critical Control Points (HACCP): Overview of Principles and Applications." Food Science & Human Nutrition Department. University of Florida. Gainesville, FL, 1996.

2 www.codexalimentarius.net

Act II: The More, the Merrier

-by Kathryn Cooper

Like anything else in life, you get out of your HACCP plan what you put in to it. More commitment, resources, time and training translates to a more effective plan that can ensure a safer product.

The scene: Plant manager, president, the HACCP auditors and you, HACCP systems coordinator. All are huddled around the boardroom table. A sinking feeling in the pit of your stomach. A heavy cloud of failure settles upon the room: Your plant has failed the HACCP audit.

The auditors' analyses enumerate a litany of failures: poor documentation, employees unclear about their roles and responsibilities, blatant food safety issues visible to even the most inexperienced evaluator. You feel the piercing, accusing stare of your managers from across the room and then...

All right, we won't go there. You can avoid this nightmarish scenario as you implement your HACCP program. Companies often fail HACCP audits, yet failure is entirely avoidable.

"A number of elements contribute to an effective HACCP plan," says Frank Schreurs, HACCP auditor under the AIB International (AIBI)/Guelph Food Technology Centre (GFTC) HACCP Accreditation Program. "These include management commitment, involvement from plant supervisors and personnel, training, implementation and measuring costs and benefits." Schreurs is manager of GFTC's Audit and HACCP Services in Guelph, Ontario, Canada, and a former quality specialist and auditor with Battle Creek, MI-based Kellogg. He's seen several approaches to HACCP development and implementation; many cases of failure are the result of poor planning, inadequate resources and lack of serious commitment. "You can tell a company is half-hearted when only the most junior personnel are available for the opening audit meeting," says Schreurs. "It is so important for senior management to demonstrate its interest and commitment to the program."

FROM THE TOP

Management can demonstrate commitment to HACCP programs by:

- Allocating resources (time and money) for program development;
- Requiring periodic reports on the progress of HACCP program development and removing barriers to progress;
- Initiating HACCP team meetings and training sessions by a reinforcing the reasons HACCP is important to the company;
- Adhering to HACCP policies while walking through the plant; and
- Ensuring there are well-defined consequences for all staff who ignore HACCP program requirements.

"Successful development and implementation of HACCP boils down to top management," says one manager of QA for a large Canadian meat processor. "Our plant manager sat through every training session we held for our 130 employees to demonstrate his commitment to the process." The results of this company's ongoing internal audits of the HACCP system are discussed at weekly management and monthly food safety meetings. The minutes from the monthly meetings are sent to the vice president of operations, who scrutinizes them. The company has also designated a vice president of food safety.

WE'RE ALL IN THIS TOGETHER

Employee involvement and input is extremely critical to effective HACCP plan development. Too often, HACCP plans and concomitant GMPs are more fiction than fact. To meet tight deadlines, the HACCP coordinator creates these documents with minimal input, closeted in the laboratory. The content then constitutes a surprise for forepersons, supervisors and on-line personnel during a HACCP audit.

"When questioning line personnel and reviewing their practices, it becomes clear whether the program was written to satisfy the standard or the actual plant activities," says Irwin Pronk, senior quality systems specialist, HACCP accreditation auditor and a former QA manager with Pillsbury. During one audit, Pronk witnessed the pitfalls of not being involved in writing one's own HACCP procedures. As the auditor questioned two managers about specific department activities, they became confused. "Half way through the discussion they asked if they could bring in the management representative who had written the documented program because they didn't know the procedures well enough," says Pronk. "How could these managers hold their employees accountable to the program if even they don't know the requirements?"

At Windsor Wafers, a Parmalat bakery that received HACCP accreditation by GFTC and AIBI, the employees played a significant role in implementing the program. "Our employees have embraced the program and made it part of their working lives," says General Manager Al Spilowey. "With this level of commitment we can assure our customers that the product we deliver meets the highest safety standards."

Employees actually performing a task develop the most effective programs. HACCP coordinators should be wary of supervisors who claim to know all that goes on at the plant floor level. Sometimes they will be surprised. If the individual writing the program does do the work, he must consult the personnel involved and submit the final document for review to ensure the information is accurate.

TRAINING 101

Training should be ongoing throughout the development and implementation of an effective HACCP program. HACCP teams must be trained as the GMPs and HACCP plans are developed. Line personnel need to be trained on GMP requirements. Individuals responsible for monitoring critical control points need explicit training to outline the nature of the CCPs, critical limits, monitoring requirements, corrective action or deviation procedures and recordkeeping.

"One of the keys to effective training is explaining 'why'," says Jennifer McCreary, a food safety trainer and former QA manager at Canada Bread. "We want everyone to understand the consequences of not following these HACCP rules from a food safety as well as an employment perspective. Furthermore, when the training sounds too scientific or analytical, people stop listening."

Some facilities must overcome special challenges to help employees understand the "whys." In one plant, 97% of the employees were Chinese, speaking Mandarin and Cantonese dialects. The trainer addressed these language barriers with on-site translation and illustrations to depict incorrect practices. Employees are awarded small prizes-mugs, tee shirts-for identifying the greatest number of noncompliance events. Some companies augment training with short daily or weekly production meetings, posters throughout the plant, white boards to track compliance and written refreshers inserted into pay check envelopes. "It is important that line supervisors and managers conduct some, if not all, of the training for the employees. Supervisors should know the area best; they are responsible for reinforcing and enforcing the requirements," says Pronk.

At one plant, every employee initially received 90 minutes of GMP training, followed by another 90 minutes of HACCP training. Supervisors responsible for reinforcing the program and verifying HACCP CCPs received a minimum of two hours on each topic. Refresher courses are given about twice a year.

PLAYS WELL WITH OTHERS

Effective HACCP implementation requires that each employee accepts responsibility and accountability everyday. Such is the case at Schmalbach-Lubeca, a HACCP-accredited PET packaging company for the food industry. "Chemical control, for instance is one of our prerequisite program requirements," says Cathy Gero, corporate quality systems coordinator, "So it is the responsibility of every person in the plant to ensure that all chemicals are kept under lock and key when not in use. Everyone understands, through the training they've completed, that chemical control is important to our process and why. A chemical container left on the production floor becomes the responsibility of the person who discovers the violation. She must ensure that the container is properly stored without relegating the job to someone else."

Creating good habits and breaking bad ones ensure accountability is accepted by employees. This involves internal audits, reinforcement and enforcement of program elements of both the prerequisite and HACCP plans. In most companies, a high level of internal auditing is required after initial implementation. At one company, this involves daily audits on each shift by QC personnel. As these audits are conducted, employees are reminded of the new requirements. Audit reports are generated to make supervisors aware of the strengths and weakness of the program. Enforcement is strict. "Sometimes it is necessary to 'write up' employees and even managers to show that a program is taken seriously," says Pronk. "The preference is always to explain why the requirement is in place and demonstrate the program's benefit to an employee; however, sometimes discipline is required." It is essential to involve the employee's direct manager in the

disciplinary process. "We need the support of the supervisors and managers in reinforcing and enforcing the implementation of these procedures. By involving the management group in the cautions, verbal warnings and written warnings, they can demonstrate their own commitment to the program," Pronk adds.

After the initial phase-in period, usually four to six weeks, the frequency of audits for the prerequisite programs can decrease. Daily checks can be conducted by the supervisors or specified line personnel, which are then supported by monthly audits by QC or members of the HACCP team. Good reporting to the management team and plant personnel is essential for everyone to know how successful the implementation process has been. Some plants post audit results in lunch rooms and expose the number of HACCP program non-compliances on notice boards at the plant's entrance.

PLUSES AND MINUSES

With a long-term, broad-scale, fully functional, effective HACCP program in place, food manufacturers can expect everyone following correct procedures, passing the HACCP audit and decreasing the number of consumer complaints.

HACCP can improve a company's bottom line. Monitoring the benefits and costs of the program enables a company to set goals around the HACCP program for continuous improvement. In the words of Management Consultant Louis Allen, "Minimizing loss is as much improvement as maximization of profit." HACCP can potentially double product shelf-life, significantly decrease retail store credits and diminish downtime. In one poultry plant, the maintenance supervisor made a significant HACCP commitment to conduct weekly preventive maintenance checks for food contact surfaces. The cost of maintenance crew overtime paid off. In just three weeks the plant was operating better, downtime was at an all-time low and plant management acknowledged the new system was superior.

Decreases in waste, rework, recalls and downtime demonstrate that HACCP's dividends extend beyond the main goal of food safety. Meeting customer requirements and expectations is imperative. Whether HACCP allows you to maintain existing market share or create new opportunities depends on your role in the food chain. For companies like Schmalbach-Lubeca, HACCP implementation could indeed generate new business. "As more and more customers become sensitized to the possibility of risk to their business and to consumers, it is reassuring to know that Schmalbach-Lubeca has stepped forward and initiated our own company-wide HACCP program in the US," says Gero. "We began the process in mid-2000 and by the close of 2001, each of our manufacturing plants received HACCP accreditation. This was an aggressive goal, but we knew this was important to our company and our customers."

Effective HACCP program design and implementation will ensure that the program is successful and cost effective. It sure beats the nightmare of failing the HACCP audit!

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