HACCP: An Overview[1]

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HACCP is a food safety management system that is used in various segments of the food industry. The objectives of this fact sheet are to introduce the topic and to summarize the key components of a HACCP program.

What is HACCP?

HACCP is a system that relies on process controls to minimize food safety risks in the food processing industry. The acronym HACCP (pronounced /'hæ-sip/) stands for "Hazard Analysis Critical Control Point". It is useful to think of HACCP as a preventative food safety system rather than a traditional quality control inspection system. HACCP is not "zero risk" and does not eliminate the possibility of a hazard getting into the food product. Rather, HACCP attempts to decrease that possibility to an acceptable level.

How does HACCP work?

Significant hazards for a particular food product are identified after a review of all the processing steps and use of scientific information. The steps at which these hazards can be controlled are identified, and critical limits (such as process temperatures and hold times) at key process steps are set. Monitoring procedures are implemented to evaluate conformance with these critical limits. Should the process fall outside these limits, pre-planned corrective actions are taken to prevent the potentially defective product from entering the commerce stream. In addition, the HACCP system relies on extensive verification and documentation to assure that food safety has not been compromised during any step. Thus, HACCP provides a risk assessment structure for putting controls in place to minimize such risks.

HACCP History

HACCP is not a new system. The concept was developed in the 1960s by the Pillsbury Company while working with NASA and the US Army Laboratories to provide safe food for space expeditions. The limitations of end product testing became evident to those who were trying to provide the safest possible food products. In order to ensure statistically that food used for space missions would be safe, almost all the product manufactured would need to be tested, leaving very little for actual use. A new approach was needed. The practical and proactive system of HACCP evolved from these efforts to understand and control food safety failures. HACCP has been widely used by industry since the late 1970s. It is endorsed by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) of the United Nations, and, in the United States, by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

HACCP and Food Regulation

The US Food and Drug Administration (FDA) used HACCP-based principles in the development of low-acid food canning regulations in the 1970s. In 1995, the FDA issued regulations that made HACCP mandatory for fish

and seafood products, and issued regulations for mandatory HACCP in juice processing and packaging plants in 2001. In addition, a voluntary HACCP program was implemented in 2001 for Grade A fluid milk and milk products under the cooperative federal/state National Conference on Interstate Milk Shipments (NCIMS) program. The FDA has also implemented pilot HACCP programs for a variety of other food processing segments as well as for retail foods. HACCP has also been implemented by the USDA. In 1998, USDA's Food Safety and Inspection Service (FSIS) mandated HACCP for the nation's meat and poultry processing plants. Currently, HACCP systems are utilized for pathogen reduction in over 6,500 raw meat and poultry plants.

HACCP and the Food Safety Modernization Act (FSMA)

The newly legislated Food Safety Modernization Act (FSMA) incorporates the mandatory use of science-based, preventive food safety programs in several segments of the food industry, including produce. Seven foundational rules provide the framework for the industry to mitigate food safety risks and afford FDA new enforcement authorities and tools to strengthen compliance. While certain exemptions may apply, any food operation or facility should be cognizant of these principles. Facility practices and classifications often change, which may cause those entities to be subject to rules at a later date. Furthermore, employing food safety mitigation strategies is a good practice, because any food supplier can impact consumer health. To successfully implement such sweeping reform, collaboration and enhanced partnerships are necessary. The seven foundational principals are found below:

- Produce Safety Rule
- Preventive Controls for Human Food
- Preventive Controls for Food for Animals
- Foreign Supplier Verification Program
- Accredited Third-Party Certification
- Mitigation Strategies to Protect Food Against Intentional Adulteration
- Sanitary Transportation of Human and Animal Food

Of these seven rules, the preventive controls rules for human and animal food are the two that incorporate some familiar HACCP-based principles to control identified hazards requiring preventive controls. Provisions regarding human food are delineated in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF) Rule. Major differences between the traditional HACCP programs and PCHF are improved and expanded principles to minimize the current burden of foodborne illness and reduce the large number of preventable recalls. While HACCP principles have been integrated into the new regulations, PCHF has been made more rigorous, such as by incorporating specific language for allergen control and including other preventive controls in addition to process preventive controls, such as supply chain and sanitation preventive controls. Similar to HACCP, PCHF is aimed at significantly minimizing or preventing known hazards or hazards that are reasonably foreseeable. Updated Current Good Manufacturing Practices (GMPs) have been reorganized from Title 21 of the Code of Federal Regulations (CFR) Part 110 to 21 CFR Part 117. Much like HACCP, some identified hazards will be mitigated by GMPs unless further control is needed; e.g., preventing recontamination of a finished product exposed to the environment. While HACCP identifies process-oriented controls that mitigate potential hazards, PCHF further differentiates hazards requiring control into five control categories mainly regarding processes, food allergens, sanitation, and the supply chain. In the event a control is established, a recall plan is required and would be considered another control, whereas for HACCP, a recall plan is not required. Furthermore, as emerging risks occur, new hazard components may need to be evaluated. Unlike HACCP, radiological concerns are now considered a potential chemical hazard, which would be relevant for facilities where these hazards could be found in the surrounding environment. Thus, the 3-year minimum timeframe to reevaluate a company's food safety plan (FSP) required for PCHF should be conducted as frequently as necessary.

HACCP is an internationally recognized program that has been implemented in many other countries (e.g., European Union countries, Canada, Australia, and New Zealand) and is a high priority program under the Codex Alimentarius, the world food safety authority. In the US, HACCP programs are still required for meat products, seafood, and fresh juice, while the new PCHF covers most other processed foods. Some entities can easily determine if the activities conducted are covered by PCHF, such as producing a frozen entrée, a breakfast bar, or a salad kit. For those entities with a more complex structure, it is recommend to submit an inquiry to FDA's Technical Assistance Network (TAN) to determine compliance, which is found on FDA's website (https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm).

Implementation of PCHF also mandates the preparation and review of the FSP to be managed or overseen by an individual qualified through adequate training or job experience. This requirement can be satisfied by a company employee or an external consultant meeting the qualifying criteria. To review further information covering the new FSMA regulations, search for FSMA fact sheets on the EDIS system (http://edis.ifas.ufl.edu).

Prerequisite Programs

HACCP is not a stand-alone program, and the necessary prerequisite programs must be in place prior to its full implementation. Prerequisite programs are practices and/or conditions needed prior to and during HACCP, which are an essential part of the overall food safety plan. Typical prerequisite programs include Good Manufacturing Practices (GMPs), raw material control programs, vendor certifications, sanitary standard operating procedures (SSOPs), and recall and traceback procedures. Examples of GMPs include sanitary facility design, proper pest control procedures, and the provision and upkeep of handwashing and sanitary facilities. SSOPs can include provisions for minimizing cross-contamination in the plant, maintenance of a potable water supply, and specific practices to ensure the sanitation of the facility and individual pieces of equipment within the facility. A foundation of effective prerequisite programs is necessary for successful implementation of HACCP.

Figure 1. Word cloud, or Wordle, illustrating many words associated with HACCPs, including GAPs, GMPs, traceback, and intervention.
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What hazards need to be controlled?

Foodborne hazards controlled through HACCP include physical, chemical, and microbiological agents that have the potential to cause an adverse health effect when a food containing them is consumed and that are reasonably likely to occur if not controlled. While consumers have historically been most concerned with chemical hazards, such as pesticide residues and heavy metal contamination, microbiological contaminants and allergens have been the recent focus of public health officials. The HACCP system addresses and controls all significant hazards associated with a particular product.

Principles of HACCP

There are seven principles integral to HACCP:

- Principle 1—Conduct a hazard analysis. Potential hazards associated with a food are identified, along with measures to control those hazards.

- Principle 2—After evaluating all processing steps, determine the critical control points (CCPs). CCPs are points in a food's production and processing at which significant hazards can be controlled or eliminated.

- Principle 3—Establish critical limit(s) for each CCP. Each CCP must operate within specific parameters to ensure the hazard is being appropriately and effectively controlled.

- Principle 4—Set up systems to monitor each CCP. Monitoring involves defining how the CCPs will be assessed, performing the monitoring at the appropriate time intervals, determining who will perform the monitoring, and, finally, maintaining the proper monitoring records.

- Principle 5—Establish corrective actions. When a critical limit is not met (a process deviation), proper actions must be taken. These can be both short- and long-term corrective actions. Appropriate records must be maintained.

- Principle 6—Establish verification procedures. Verification is used to confirm that the system is working properly and that procedures outlined in the HACCP plan are being followed.

- Principle 7—Record-keeping and documentation. This includes all records required in the various parts of the HACCP plan, as well as other key records such as sanitation logs, supplier agreements, and shipping documents.

Future of HACCP

Domestic and international food regulators have increasingly focused on HACCP as a mandatory requirement for food processors and food handlers. With the advent of FSMA regulations, HACCP or HACCP-like systems will be mandated in additional segments of the food system for food facilities required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (unless an

exemption applies), including retail operations, certain fruit and vegetable packers, and production operations.

HACCP is an essential tool for managing food safety. However, merely legislating HACCP does not guarantee food safety. For HACCP to be effective in a food handling or processing facility, the HACCP plan must be properly developed, effectively deployed, and continuously reviewed and improved.

Sources

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