From Hazard to Prevention: How HARPC is Shaping the Future of Food Safety

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Introduction

Food safety has emerged as a critical global priority, with foodborne diseases affecting millions annually (Petrescu et al., 2020). The World Health Organization estimates that unsafe food leads to 600 million cases of foodborne illnesses and 420,000 deaths each year. These statistics highlight the need for robust food safety systems that focus on prevention rather than reaction (Elayis et al., 2024). In response, the adoption of a risk-based approach has revolutionized food safety management, moving from traditional hazard-focused methods to more proactive, preventive strategies. One of the key frameworks in this paradigm shift is the Hazard Analysis Risk-Based Preventive Controls (HARPC) system, introduced under the U.S. Food Safety Modernization Act (FSMA) in 2011. HARPC emphasizes proactive risk management throughout the entire food supply chain, from production to consumption, ensuring hazards are identified and controlled before they cause harm (Koutsoumanis & Aspridou, 2016). This system builds on the foundation of the Hazard Analysis Critical Control Point (HACCP) approach but extends its scope to address a broader range of food safety risks, including biological, chemical, and physical hazards (Barlow et al., 2015). The shift to HARPC reflects a more precise and systematic approach to food safety, enabling food producers to anticipate and mitigate risks effectively and ensuring safer food for consumers worldwide. This article explores how HARPC transforms traditional food safety practices, focusing on its role in the food industry, and the broader implications for global food safety.

From HACCP to HARPC: A shift in food safety frameworks

In the United States, food safety practices have long been built around the Hazard Analysis Critical Control Point (HACCP) system. It was developed in the 1960s and focuses on identifying critical control points in the production process to minimize the risk of contamination (Sperber, 2005). While HACCP has been instrumental in improving food safety, recent evaluations by the U.S. Food and Drug Administration (FDA) revealed limitations in addressing certain emerging food safety risks (Malik et al., 2021).

In response to these concerns, the U.S. enacted the Food Safety Modernization Act (FSMA) in 2011, with the aim of overhauling the existing food safety approach. The FSMA places a stronger emphasis on preventive controls, marking a departure from the traditional reactive methods. Section 103 of the FSMA introduced HARPC as a requirement for food producers, signalling a shift toward a more comprehensive and risk-based approach to food safety (Brackett et al., 2014).

What Is HARPC?

HARPC builds upon the HACCP framework but takes a more preventive and systematic approach to food safety. While HACCP focuses on identifying and controlling hazards at critical points, HARPC expands the scope to address a wider array of potential risks, ranging from biological and chemical hazards to physical contamination and allergens (Laborde, 2020). HARPC requires food producers to take a holistic view of their production process, from raw material handling to distribution and storage, to proactively identify and mitigate risks.

Under HARPC, food safety is not just about responding to contamination when it occurs but preventing it from happening in the first place. This is achieved through a set of preventive controls that target hazards before they become a problem. These controls are integrated into all stages of food production, ensuring that food safety is consistently monitored and managed (Abeo, 2021).

Key Components of HARPC

HARPC consists of seven principles (shown in Fig. 1. that form the core of the food safety management system. These steps are designed to ensure that food producers can identify, assess, and manage risks effectively (LaBorde, 2020).

- Identifying hazards that encompass biological, chemical, and physical risks, while also encompassing both deliberate and unintentional sources of contamination
- Establishing preventive controls, which incorporate an environmental monitoring program aimed at averting potential hazards.
- Routine monitoring of the effectiveness of these controls.

- Developing comprehensive corrective actions, including provisions for a recall plan in case of safety breaches.
- Verification of the proper functioning of the steps outlined in the HARPC plan.
- Mandated recordkeeping and documentation, which are now obligatory according to FDA regulations, and must be made available upon request, whether written or verbal.
- Re-evaluating the Hazard Analysis Risk-Based Preventive Controls plan at defined intervals of every three years, or before any significant operational changes occur (Wester, 2017; LaBorde, 2020 and DeMarini et al., 2024).

Fig. 1. Seven principles of HARPC

Preventive Controls Under HARPC

The Food and Drug Administration (FDA) has established six distinct classes of preventive controls (Fig. 2), with each category mandating the integration of monitoring, corrective action, verification, and record-keeping protocols (LaBorde, 2020).

Process Preventive Controls

They encompass a set of protocols, practices, and methodologies strategically designed to effectively oversee and mitigate anticipated hazards that may arise at specific junctures. For each process of preventive control, it is imperative to establish explicit "parameters and values" that serve as indicators of the successful management of potential hazards. A robust monitoring system is required to promptly detect any loss of control, and in case of control failure, corrective actions must be promptly implemented. Suppose an organization already has a HACCP plan. In that case, it can readily integrate previously established CCPs (critical control points) critical limits, monitoring procedures, and corrective actions into the HARPC food safety plan (Malik et al., 2021). Some examples of process controls are given in Fig. 3.

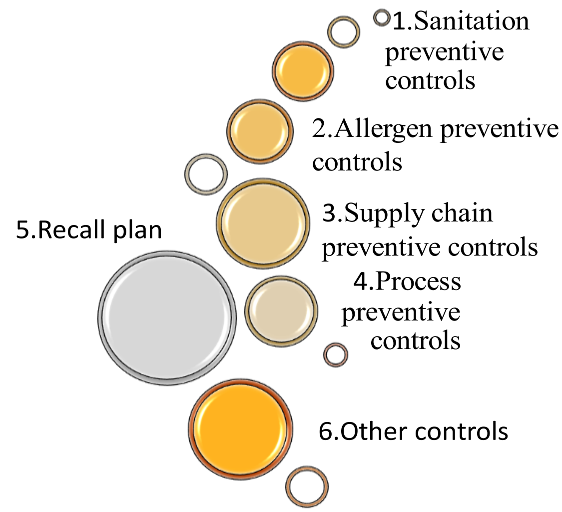

Fig. 2. The six different types of preventive controls

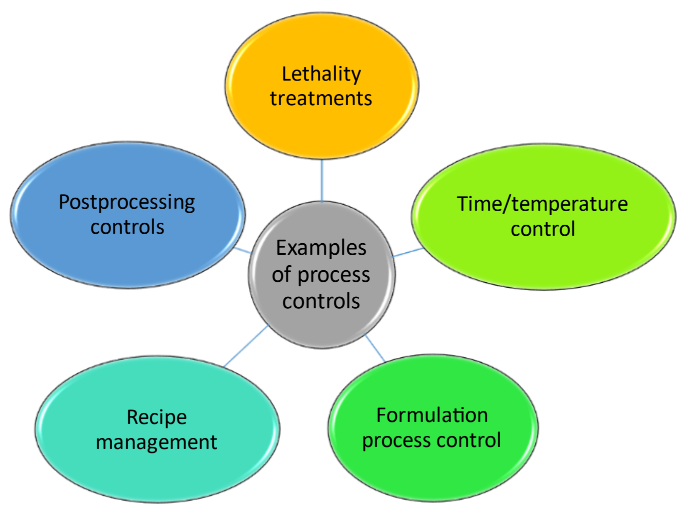

Fig. 3. Examples of process controls in food industry

Sanitation Preventive Controls

They encompass a set of procedures and regulations devised to effectively cleanse and disinfect surfaces that come into contact with food, mitigating the potential for the transmission of microorganisms and chemical contaminants, and actively monitoring the presence of environmental pathogens. While within the Hazard Analysis and Critical Control Points framework, concerns related to inadequate sanitation practices were typically managed through prerequisite programs, the advent of the Preventive Controls Rule has now mandated food manufacturers to address and prevent sanitation deficiencies more rigorously within the context of the Hazard Analysis and Risk-Based Preventive Controls plan. This shift is prompted by the escalating occurrences of outbreaks and recalls linked to contamination of ready-to-eat foods post-processing.

In cases where minor and isolated sanitation deficiencies are identified, which can be promptly rectified, the FDA (Food and Drug Administration) allows for immediate "corrections" without the full suite of corrective actions mandated by a Hazard Analysis and Critical Control Points plan. However, if unsanitary conditions persist over an extended period or present an imminent and significant threat to consumer safety, more comprehensive corrective measures may be necessitated (LaBorde, 2020).

Allergen Preventive Controls

They encompass a set of methodologies, protocols, and operational procedures that are implemented to ensure the precise and accurate labeling of food-allergenic components in both the ingredients and the final food products. Additionally, these controls are designed to prevent the inadvertent cross-contamination of allergenic substances during the various stages of food processing. Adherence to the regulatory mandates outlined in the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (FDA, 2004) is essential to forestall unintentional health consequences in individuals who are hypersensitive to allergens such as milk, tree nuts, eggs, tree nuts, shellfish, soy, fish, peanuts and wheat. Monitoring activities within this context may encompass routine assessments to detect instances of mislabeling in ingredient listings, visual inspections following cleaning processes, and the application of allergen test kits to evaluate the potential risks associated with allergen cross-contamination. Corrective actions are mandated when the monitoring results indicate that the existing preventive measures are insufficient to mitigate allergen exposure risks to the public. Depending on the outcomes of the hazard analysis, certain allergen-related hazards can also be effectively managed through the incorporation of sanitation and supply chain preventive controls or within the framework of prerequisite programs (Wester,2017).

Supply Chain Preventive Controls

They encompass a series of systematic measures and protocols designed to mitigate or diminish the risks associated with ingredients or raw materials used in food production. These measures are the responsibility of the supplier and require diligent monitoring by the food manufacturer. Supply chain controls may encompass activities such as verifying the presence of a certificate of analysis (COA) accompanying each shipment, conducting on-site inspections to ensure adherence to food safety standards, or relying on findings from third-party audits. In circumstances where no other preventive controls are deemed capable of adequately addressing foreseeable hazards, a supply chain prerequisite program can be elevated to preventive control status within the Hazard Analysis and Risk-Based Preventive Controls plan (Malik et al., 2021).

Recall plan

Recalls involve removing adulterated, misbranded, or violative products from the market (Food Safety Preventive Controls Alliance, 2016). In 2015, the FDA reported approximately 600 recalls affecting 3,000 food products (U.S. Food and Drug Administration, 2015). Before FSMA, recalls were voluntary; the FDA could only encourage companies to act. FSMA now allows the FDA to mandate recalls after giving companies the opportunity for voluntary action (U.S. Food and Drug Administration, 2016).

Recalls are classified as:

- **Class I:** Serious health risks or death (e.g., botulinum toxin, undeclared allergens).
- **Class II:** Temporary or minor health risks.
- **Class III:** Minor regulatory violations without health risks (U.S. Food and Drug Administration, 2015c; Undated).

Manufacturers must have a written recall plan detailing procedures for notifications, public communication, recall effectiveness verification, and product disposition (U.S. Food and Drug Administration, 2016).

Other controls

According to 21 CFR Part 117.135, "other controls" refer to procedures, practices, and processes necessary to significantly minimize or prevent hazards requiring a preventive control. These controls apply to hazards not covered by the five main preventive control categories and may include examples like hygiene training and other cGMPs (Laborde, 2020). The focus should remain on ensuring that each identified hazard requiring a preventive control is effectively addressed, regardless of its specific categorization.

The Benefits of HARPC

The shift from a hazard-focused approach to a risk-based system has significant benefits for food safety. By focusing on prevention rather than reaction, HARPC helps food producers reduce the likelihood of foodborne illnesses, allergic reactions, and other food-related hazards. This proactive approach is more effective in protecting public health and reducing the financial and reputational costs of food safety incidents (Malik et al., 2021). Additionally, HARPC allows for greater flexibility in addressing the unique risks associated with different products and facilities. Each food producer is required to develop a customized food safety plan based on the specific hazards present in their operations, allowing for more tailored and effective risk management (Laborde, 2020).

Conclusion

HARPC represents a crucial evolution in food safety management, responding to the growing need for more preventive and risk-based approaches to food production. By building upon the principles of HACCP, HARPC offers a more comprehensive and flexible framework for identifying, managing, and mitigating food safety hazards. As the food industry continues to evolve, the adoption of HARPC and similar risk-based approaches will play a pivotal role in ensuring the safety of the global food supply chain and protecting public health.

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