

# IS HACCP ENOUGH FOR ENSURING FOOD SAFETY?

BY LARRY KEENER

*Recent foodborne illness outbreaks suggest that HACCP should be used in a broader context.*

Implementing strategies for ensuring the safety of the food supply is a key and fundamental activity for food processors, foodservice operations and regulatory agencies. Events of the recent past clearly demonstrate that food safety failures portend dire, if not devastating, consequences for the food manufacturer or foodservice vendor. These events have stimulated a national dialogue centered on food safety. The primary focus of the dialogue is containment and methods for ensuring safe manufacturing, distribution, storage and service of food products.

Hazard Analysis & Critical Control Points (HACCP) procedures, a science-based approach for ensuring food safety, is generally regarded by food safety experts and regulatory officials as the method of choice as opposed to traditional inspection and testing based procedures. HACCP was developed jointly by the Pillsbury Co., NASA and the U.S. Army National Research Laboratories specifically for ensuring the safety of the foods intended for use in the manned space program. At that time, it was recognized that the conventional inspection-based methods were not suited to ensuring food safety. HACCP involves hazard identification and the development of specific countermeasures to mitigate potential hazards. The system has proved an effective control strategy.

Over the past 40 years, the HACCP approach has gained broad support from both government and industry. After a

major *C. botulinum* outbreak in the early seventies, the U.S. Food and Drug Administration (FDA) issued the low acid canned food regulations.<sup>2</sup> These regulations are often cited as the first government-mandated HACCP program. Today, mandatory HACCP programs are in place at both FDA- and U.S. Department of Agriculture (USDA)-regulated segments of the food industry. Evidence of voluntary HACCP development is also widespread throughout the food processing and foodservice industries.

HACCP is currently extolled as a panacea for government and industry food safety failure prevention. But is HACCP alone sufficient for ensuring food safety?

## THE SCOPE OF HACCP

Within the last two years there have been several highly publicized food safety failures that have occurred in federally inspected establishments operating under approved HACCP plans. In two of the more notorious episodes, the public record indicates that the root cause of the failures were in fact not related to the HACCP plans. In one case, it is reported that product contamination resulted from a lack of Good Manufacturing Practices (GMPs) in the handling and storage of rework materials. In another incident, the contamination is reported to have resulted from a failure in the sanitation program. Nonetheless, the companies directly involved were financially devastated and the broader food industry's reputation for safety was further maligned.

Sound prerequisite programs are essential to the successful development and implementation of a HACCP plan. Generally, it is industry practice not to include the prerequisite programs in the formal HACCP plan. Industry has longstanding concerns related to the potential for increased regulatory authority associated

with a broadly written HACCP plan. While it is true that these programs are not components, per se, of the HACCP plan; it is also true that they contain activities that are critical to achieving food safety. The supporting programs should be viewed as elements of a broader, more comprehensive food safety system. HACCP alone, without the contributions of these supporting programs may not be an effective aegis against a food safety failure. Sanitation, GMPs, quality control (QC), and regulatory compliance programs are essential to the development of a robust, reliable and sustainable food safety system.

Most U.S.-based food processors have these basic programs in place. However, many fail to view these elements and their subordinate activities as components of a comprehensive food safety system. Consequently, the management of these companies frequently have a feigned view of the effectiveness of their food safety efforts. Moreover, because of this myopic view, companies often experience difficulty in sorting through the financials and in developing appropriate funding for this important business activity.

The success and reliability of HACCP for ensuring a product's safety is largely dependent on adhering to the seven fundamental HACCP principles.<sup>1,2</sup> The seven principles are as follows:

1. Hazard Analysis
2. Critical Control Points
3. Establish Critical Limits
4. Monitoring
5. Corrective Actions
6. Recordkeeping and Documentation
7. Verification

Of these precepts, perhaps the most fundamental and important to the success of the plan is verification. This principle requires that steps are provided that will ensure that the HACCP plan is work-

ing. Similarly, the success of the comprehensive food safety system is also dependent on verification procedures. Verification protocols must be an effective means of identifying a breach in procedures or a general loss of the program's integrity. The procedures must be directed toward providing management a clear and

alone is not sufficient for ensuring food safety. Each element and its subordinating activities must be coordinated and linked with the HACCP plan to form a food safety system. USDA recognized the importance of this relationship when the agency linked sanitation (SSOPs) to its mandatory HACCP programs.<sup>4</sup> To

ation of the ability to execute against program expectations and also of the overall management process.

When properly planned, implemented and executed, HACCP has proved an effective strategy for preempting food safety failures. However, recent foodborne illness outbreaks suggest that HACCP alone, without the coordinated contributions of proven GMP, sanitation, quality control, and regulatory compliance programs may not provide adequate protection against an unpropitious food safety failure. While not part of the HACCP plan, these supporting programs do contain elements and activities that are critical to achieving food safety. The recent spate of foodborne illness outbreaks further suggests that HACCP is a management tool, a singular element, that should be used in the context of a broader program designed to protect against a food manufacturing or distribution failure with associated public health implications. 

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## COMPREHENSIVE FOOD SAFETY SYSTEM

### Food Safety Umbrella

Quality • Regulatory • HACCP • GMPs • Sanitation  
 Manufacturing Supply Chain  
 Feedback Mechanism  
 Improvement  
 Products • Processes • Productivity • Performance

Source: International Product Safety Consultants

concise view of the effectiveness of the company's food safety efforts.

Verification procedures may be viewed as two distinct but commonly focused activities: (1) An in-depth evaluation of each of the principle elements of the program; and (2) an evaluation of the interactions amongst the various elements of the system. The in-depth evaluation of the primary elements of the system should measure the effectiveness of the element in achieving industry and government standards and expectations. For example, in evaluating the effectiveness of a GMP program, attainment of the standards codified in FDA's current Good Manufacturing Practices Regulations may be satisfactory.<sup>3</sup> That is, does the program fulfill the basic requirements for process control, warehousing and storage, control of undesirable microorganisms, buildings and facilities, component sourcing, and training of plant personnel? It is not only conceivable but highly likely that failure to achieve this standard may result in a food safety failure which may not necessarily have been identified in the HACCP plan. A similar case can be made for each of the other fundamental elements that together constitute the food safety system.

Attainment by the individual elements of government and industry standards

achieve optimal performance of the food safety system requires similar linkage between each of the various elements. Sanitation must be linked with quality control and likewise, quality control linked with regulatory compliance and so on. Certain linkages and relationships are more important than others in achieving food safety. Arguably the interaction between quality control and regulatory compliance is not as important as is the linkage between GMPs and HACCP, for example, in achieving food safety.

Proper analysis of the relationships and integration amongst the elements is essential for predicting the overall effectiveness of the food safety system. A high degree of integration corresponds with maturity, timely execution and efficacy of the entire food safety program. Too high a degree of integration can be indicative of duplication and excess. Mastery of the component interaction process indicates a cost-effective food safety program with minimum risk.

The overall effectiveness of a comprehensive food safety system is properly measured by assessing the efficacy of the individual program elements and evaluating the degree to which the elements interact or coalesce to form a coherent system. The assessment involves an evalu-