Adopting a Risk-Based Preventive Approach to Food Safety Across the Complex Supply Chain

The food industry is under tremendous pressure to regain consumer trust by delivering safe and high-quality food while meeting regulatory requirements across its complex supply chain.

Significant growth in the number of food safety incidents, increased international media scrutiny, and evolving regulatory requirements have put the responsibility on the food industry to source, produce, and deliver safe and high-quality food. The food industry is currently under tremendous pressure to regain consumer trust by delivering safe and high-quality food while meeting various regulatory requirements across its complex supply chain. Every operation is unique and organizations need to take adequate initiatives to identify and assess risks and take precautionary measures to nip potential food safety incidents in the bud and comply with the regulatory mandates. There is a real need to have a risk-based preventive approach in which data and expertise are marshaled to pinpoint potential food-safety issues along the production, distribution, and handling chain. Thus, a proactive approach to food safety will help organizations avoid food-safety incidents and will result in improved brand reputation and customer loyalty.

RISK-BASED APPROACHES

A risk-based, preventive food-safety system can be developed by leveraging Hazard Analysis and Critical Control Points (HACCP), which is the primary risk-management system used by the food industry. HACCP provides a systematic preventive approach to food safety from various types of hazards in production processes that can
Food Safety

cause the finished product to be unsafe. It also helps to design measurements to reduce these risks to a safer level.

The Food Safety Modernization Act (FSMA) proposed rule, Hazard Analysis and Risk-Based Preventive Control (HARPC), also can be leveraged to create a culture of preventive food safety. On January 2013, the FDA issued a proposed rule implementing the HARPC provisions of FSMA. The proposed rule applies to certain unintentional hazards, such as microbiological, chemical, physical, or radiological hazards that may occur at a food facility that manufactures, processes, packs, or holds human food. While HACCP necessitates evaluations for biological, chemical, and physical hazards, the proposed rule for HARPC extends it to radiological hazards as well. As written in HARPC, each facility will need to conduct an analysis to determine what the risks are for radiological hazards; and, if there is a reasonable likelihood of radiological hazards occurring, the organization would need to define its specific control measures for those hazards.

Hazard research is another essential component of HARPC. The industry needs to be able to show to regulators and auditors the research it has done to conclude any component as hazardous. This is significantly different from HACCP regulations under FDA in which there are guidelines published about the unique hazards for the seafood and juice industries.

In the case of a critical control point, HACCP requires organizations to validate it, or show evidence that it does in fact control the identified hazard. The same concept of HACCP is applied, but in a broader sense. HARPC can be applied to all preventive controls across the organization. These additional components in the proposed rule for HARPC, which will soon be a mandate, can be added to the HACCP program to create an efficient risk-based preventive food safety program.

IDENTIFYING HAZARDS
Identifying hazards is the first step in preventing a food safety incident. The Bad Bug Book published by FDA outlines food items and their associated pathogens. Additionally, research can be conducted on the types of recalls that have occurred with a particular ingredient or a particular food product. FDA has identified specific types of hazards for agricultural products related to pesticides and fertilizers and the potential contamination of the water supply.

Allergens are another issue. Producers have to refer to the Big 8 allergens that must be controlled while making product for the U.S. For other countries, however, different allergens must be controlled, since allergic reaction is based on the collective immune system of a particular population and are not common globally.
Similarly, hazards in processing environment and process steps should be identified. Keeping track of the supplier’s history is also essential.

**PREVENTIVE CONTROLS CREATION**

Prevention requires control and consistency of raw materials, the processing environment, and process steps. Consistency of the raw materials can be ensured by using only dedicated suppliers. Processing environment hazards and risks can be controlled by having very rigorous, robust prerequisite programs such as sanitation control, pest control, allergen control, chemical control, etc. Preventive controls for process steps can be achieved through process specification such as time, temperature, pressure, humidity, etc.

Every operation, hazard, and risk is unique, and specific limits and activities to control these are essential in creating preventive controls. For example, not all pathogens are created equally. *Salmonella*, *bacillus cereus*, and *clostridium botulinum* each require unique control measures. Allergen control specific to each hazard is also essential. For example, the cleaning method that is effective in allergen removal for whey powder on stainless steel may not be effective for almond paste on UHMW plastic. Each control, or cleaning method, must be validated based on the soil and the surface.

**VALIDATION AND VERIFICATION OF PREVENTIVE CONTROLS**

Validation is the most important part of any food safety program. Scientific literature can be used as validation, including such things as white papers, writings published in scientific journals or university studies, and challenge studies that are done within scientific journals or university studies, as white papers, writings published in scientific journals or university studies, and challenge studies that are done within scientific journals or university studies.

Verification is another important part of the food safety program. It is done by ensuring compliance to the preventive-approach plan that the company has established. For example, as a verification process, companies should confirm whether sanitation, allergen control, chemical control, and process control are being followed exactly as designed.

**TECHNOLOGY STRATEGIES**

Technology enables companies to adopt an integrated approach to food safety programs. The solutions available in the market are packed with strong capabilities and functionalities empowering companies to adopt a workflow-based approach, automate and streamline key processes, eliminate silos, and seamlessly achieve the desired results from the risk-based preventive food safety program.

This includes:

- **Compliance management:** Companies can leverage technology to centrally manage compliance standards and requirements mapped to relevant country, business units and processes, products, and suppliers. Central repositories with strong document-management functionalities help with recordkeeping.
- **Supplier and product information management:** Sophisticated web-based solutions simplify the process of capturing and managing supplier and product information including sub-suppliers, lab, testing, verification and validation on preventive control, country of origin, and transit information.
- **Hazard analysis and risk management:** Technology helps automate the end-to-end hazard analysis and risk-management processes. Solutions include templates to facilitate hazard classification and tools such as risk heat maps, risk calculators, and scorecards for hazard analysis and risk assessment. These help in enhancing the process of identifying, evaluating, and prioritizing food quality and safety risks including supplier and supply chain risks. The solutions are equipped with risk-ranking and -ranking capabilities, and help to determine the impact, likelihood, severity, and frequency of hazards and risk in a simple and consistent manner. Companies also can confidently manage a centralized hazard database for easy reference and mitigate these risks and hazards.
- **Preventive controls management:** Advanced solutions help in creating and managing preventive controls for CCPs and non-CCPs including process controls, food allergen controls, sanitation controls, recall plan, environment monitoring, supplier verification, and training. It also can link controls to identified hazards and centrally manage scientific and technical information to determine if controls are adequate. It can leverage industry-based methodologies for validation of preventive controls, such as product testing and environment testing.
- **Audit and inspection management:** These solutions help in conducting audits including internal, quality, and safety audits. Companies also can efficiently conduct controls monitoring. Cutting-edge, audit-management solutions provide companies with the ability to centrally manage audit resources, schedules, and checklists. Offline audit solutions pave the way for gathering of audit data even in remote locations which are not connected to the central corporate network and have no Internet access.

A risk-based preventive approach to food safety is critical. An integrated technology solution can help maintain a central repository for managing multiple compliance standards and requirements, thus ensuring compliance with the law. At a time when the food industry is under pressure to regain consumer trust following a series of food safety incidents worldwide, a preventive approach to food safety can go a long way in ensuring safe food, regaining consumer trust, and protecting the brand image of companies operating in this field. With a preventive approach in place, organizations can ensure quality products, assure minimal number of product failures and recalls, and minimize spending on such issues. AIB

The authors are Associate Vice President of Industry Solutions, MetricStream, and Vice President, Food Safety Services Innovation, AIB International.