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to prevent gaps in controlling and managing food safety risks

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Despite continued progress in improving the quality and safety of foods produced in this country, **food safety is still a serious public health concern.**

More people consume commercially processed or prepared foods than ever before, and at the same time there is increased consumer demand for "fresh" foods in convenient, ready-to-cook forms. These demands have fostered the development of sophisticated processing and packaging systems that can significantly extend the shelf-life of various foods.

Unfortunately, these same new food products, new packages, and new methods of distribution and consumption have presented a variety of food safety challenges, such as:

- Sanitation,
- Environmental monitoring,
- Intentional adulteration,
- Raw materials,
- Equipment,
- Supplier risk assessment,
- Root cause analysis,
- Food Safety Modernization Act (FSMA), and
- Foreign Supplier Verification Program (FSVP)

Thankfully, the United States food supply is among the safest in the world. Yet, despite continued progress in improving the quality and safety of foods produced in this country, food safety is still a serious public health concern.

Regulatory enforcement

Until recently, the government's strategy for ensuring food safety emphasized facility inspection and end-product testing. While effective for many years, this approach has become outdated. The sheer number of potential contaminants, the concerns about their toxicity even at very low levels, and the difficulty and expense associated with many of the analytical methods used to quantify their levels in food make exhaustive endpoint monitoring of the food supply by government agencies virtually impossible.

The industry's size and diversity also stress the current food safety assurance program. **The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) each have a unique responsibility for food safety.**

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FDA is the agency of the U.S. Department of Health and Human Services (DHHS) responsible for the safety of all food products and ingredients, except foods regulated by USDA's Food Safety and Inspection Service (FSIS), which is responsible for the safety, wholesomeness, and accurate labeling of meat, poultry, and egg products.

Sanitation

All food establishments, whether FDA- or USDA-regulated, are required to maintain sanitary conditions to ensure the safe production of food. Sanitation failures have been illustrated by many industry food safety recalls. For example, there is the lunchmeat Listeria recall, which resulted in nine tragic deaths. Inspections revealed severe issues, including leaks from the roof, mold on walls, and pooled water and blood on the floors—conditions that create a hazardous environment for food safety.

Additionally, storage areas showed items stored directly on floors, a lack of pest monitoring, and evidence of employees eating in these spaces. Such negligence underscores the critical need for stringent sanitation practices to protect consumer health.

Current Good Manufacturing Practices

FDA-regulated facilities are subject to Current Good Manufacturing Practices (cGMPs) regulations. The cGMPs address personnel cleanliness and habits, conditions of buildings and facilities, use and maintenance of equipment and utensils, implementation of production and process controls, and conditions of warehousing and distribution. USDA-regulated establishments are subject to similar sanitation requirements as part of the Agency's mandatory inspection program.

Contamination

Poor sanitation can cause harmful food contamination, which has resulted in foodborne illness and even death in countless cases. Despite the serious consequences, some establishments have failed to take sanitation seriously.

They have relied heavily on agency inspectors to identify sanitation requirements and deficiencies instead of taking the initiative to find and remedy unsanitary conditions. This reactive approach has posed problems in all segments of the food industry.

One element of this new approach is the implementation of Hazard Analysis and Critical Control Points (HACCP) in meat, poultry, seafood, and juice establishments.

While simple in concept, **HACCP is a sophisticated and powerful system for ensuring food safety.** It requires establishments to identify the food safety hazards that are most likely to occur, and then implement effective measures to prevent, eliminate, or reduce the hazards from occurring.

Sanitation standard operating procedures

Sanitation programs are a requirement across food facilities, but the form they take depends on the regulation and type of food product produced. Under USDA inspection, establishments regulated by Food Safety and Inspection Service (FSIS) must develop and implement written Sanitation Standard Operating Procedures (SSOPs) that describe the daily pre-operational and operational sanitation procedures, identify the personnel responsible, and include

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monitoring, corrective actions, and records. FDA, however, does not have a regulation that requires SSOPs for all human food facilities.

Instead, FDA-regulated food processors must comply with Current Good Manufacturing Practices (cGMP) (21 CFR 117, Subpart B), and in some cases implement sanitation controls as part of their Preventive Controls plan when the hazard analysis determines it is necessary, such as in ready-to-eat operations or when shared equipment poses an allergen cross-contact risk (21 CFR 117, Subpart C). In juice (21 CFR 120) and seafood (21 CFR 123), processors are specifically required to implement sanitation controls, often referred to as SSOPs, though the regulatory requirements differ in whether these must be written.

For other categories, such as dietary supplements and infant formula, FDA requires written sanitation-related procedures under their respective CGMP regulations, but these are not called SSOPs.

Equipment

Maintaining equipment in good repair and adjusting per manufacturer specifications helps ensure that equipment will continue operating as designed. For example:

- A refrigeration unit in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at safe temperatures.
- The cutting or piercing parts of can openers may accumulate metal fragments that could become foreign objects in food.
- Faulty measurements could result from improper or routinely calibrated devices.
- In warewashing equipment, pressure below the designed pressure will result in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the utensil surfaces.

Harborage areas

Difficult-to-clean equipment poses significant challenges in maintaining food safety, as it can create harborage sites for bacteria. For instance, fraying conveyors and rubber scrapers introduce foreign material hazards into food products, increasing contamination risks.

Additionally, buckling or eroding floors with pooling water further contribute to unsafe conditions.

Facilities must have a plan in place to mitigate these risks until repairs can be made. This should include increased monitoring of affected areas, such as implementing extra swabbing protocols to ensure cleanliness and safety in food production environments.

Inspection tips

- Examine all equipment and utensils for cleaning suitability and accessibility.
- Determine if equipment is constructed or covered to protect contents from dust and environmental contamination. Open inspection ports to check inside if this can be done safely. Notice whether inspection ports have been painted over or permanently sealed.

When corrective actions are not initiated promptly following positive results, the risk of contamination increases, undermining the effectiveness of the entire food safety plan.

- Check the sanitary condition of all machinery. Determine if and how the equipment is cleaned before each use. If the equipment is being rented or leased, determine if it was previously used for substances that could be a source of cross-contamination.
- Inspect conveyor belts for build-up of food, cleaning solvents, lubricants, or other residual materials. Look in inspection ports and other hard-to-reach places (i.e., inside, around, underneath, and behind equipment) for evidence of filth, insects, and/or rodent contamination. Chutes and conveyor ducts may appear satisfactory, but rapping on them with the heel of your hand or a rubber mallet may dislodge static material.
- Determine how brushes, scrapers, brooms, and other items — used during processing and on food-contact surfaces — are cleaned, sanitized, and stored. Evaluate the effectiveness of the practices observed.

Evaluate any repairs made to the equipment to determine if they are permanent. Temporary parts can often break or rupture, thereby contaminating the food. Failure to maintain equipment can easily result in violations that place the consumers' health at risk.

Environmental monitoring

Strict adherence to established monitoring procedures is crucial in any food processing environment. This includes maintaining a consistent swab frequency and implementing appropriate corrective actions when deviations are identified. Failure to follow these procedures jeopardizes food safety and can lead to a breakdown of trust in the facility's safety protocols.

Swabbing

Regular swabbing is essential for detecting potential contaminants as part of an environmental monitoring program. **When corrective actions are not initiated promptly following positive results, the risk of contamination increases, undermining the effectiveness of the entire food safety plan.**

For instance, deficiencies in the Food Safety Modernization Act (FSMA) requirements from the FDA can arise when facilities neglect proper monitoring procedures, leading to increased contamination risks.

Coverage of high-risk areas

An effective environmental monitoring program must prioritize high-risk areas that are often the source of contamination. Unfortunately, it is not uncommon for high-risk zones to be overlooked in swabbing schedules.

Additionally, if swabbed areas do not align with sanitation controls or hygienic zoning specified in the food safety plan, this can create vulnerabilities. A thorough assessment should ensure that all critical areas are included in the monitoring schedule and that swabbing locations are strategically chosen to enhance sanitation efforts.

Clarity in zone definitions

Another significant challenge in environmental monitoring is the lack of clearly defined zones within the facility. **Without a well-structured zoning system, it becomes difficult to implement and maintain effective sanitation practices.**

Clear zone definitions help prioritize cleaning protocols and monitoring activities, allowing for more targeted and efficient control measures. This clarity is vital for

identifying specific areas requiring more stringent monitoring and intervention based on contamination risk levels.

Foreign Supplier Verification Program

The Foreign Supplier Verification Program (FSVP) is a critical framework to ensure that imported foods meet U.S. food safety standards. However, many companies fail to develop adequate plans to comply with FSVP requirements under the FDA. This lack of preparation can leave organizations vulnerable to significant risks associated with food safety.

For instance, when companies purchase products from brokers or distributors without vetting their FSVP plans, they inadvertently expose themselves to potential hazards that may originate from their suppliers. Such oversights can result in serious health concerns for consumers, as demonstrated by incidents like the discovery of high arsenic levels in imported apple juice sold by large retailers.

Challenges in storage and compliance

A crucial aspect of effective FSVP implementation is vetting storage conditions for imported foods. Many companies neglect to assess the warehouse environments used by their suppliers, overlooking essential factors such as cold chain management, pest control, and ensuring that storage facilities meet food safety requirements.

Inadequate storage practices can degrade food products, compromising their safety and quality. This gap in oversight can have severe consequences, including product recalls and damage to a company's reputation. **When safety protocols are not rigorously enforced, the risk of distributing unsafe products increases, putting public health at risk.**

Deficiencies

Organizations struggling to meet FSVP requirements may be issued Form FDA 483 (Inspectional Observations), which indicates objectionable conditions observed during inspections. A Form 483 serves as a notification to companies that corrective actions are necessary and highlights specific areas of non-compliance. Repeated 483s can escalate to Warning Letters or Import Alerts under FDA's regulatory authority. Failing to address the issues raised in a 483 can lead to increased scrutiny from the FDA, potential holds on shipments, and even more severe regulatory actions.

Intentional adulteration

Effective food safety management requires thoroughly assessing every food handling and production step. Unfortunately, many organizations still rely on outdated checklist formats that do not adequately capture the complexities of modern food safety regulations. This can lead to significant vulnerabilities in their operations.

Without a complete assessment, critical points in the process may be overlooked, increasing the risk of foodborne hazards. For example, the FDA inspects facilities to ensure compliance with the Intentional Adulteration (IA) Rule, which emphasizes the need to systematically evaluate potential vulnerabilities throughout the food supply chain.

When safety protocols are not rigorously enforced, the risk of distributing unsafe products increases, putting public health at risk.

Mitigation strategies

Another pressing issue is the failure to define clear mitigation strategies for identified risks. When organizations do not establish specific protocols to address vulnerabilities, they lack a proactive approach to risk management.

This is particularly concerning in scenarios like unloading incoming bulk tankers, where the absence of on-site supervision or monitoring—such as cameras—can lead to critical safety lapses. If there are no established strategies to mitigate risks at these vulnerable points, the safety of the food supply is compromised, exposing consumers to potential contamination.

Verification of records

Documentation is essential for demonstrating compliance during inspections and consistently following safety protocols. Without proper records, organizations cannot effectively track their adherence to food safety standards, which may lead to regulatory repercussions and a loss of consumer trust.

The absence of these records can further hinder efforts to identify trends and areas for improvement, undermining the overall effectiveness of a food safety program.

Implementation

Implementing effective food safety measures is often worsened by a lack of internal expertise and incomplete training initiatives. **Many organizations lack adequately trained personnel familiar with the complexities of food safety regulations.**

This knowledge gap can hinder the establishment of robust safety practices and may result in oversights during inspections. For instance, when companies fail to complete the necessary training, employees may be unable to identify potential vulnerabilities or execute proper safety protocols, further jeopardizing food safety.

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Raw materials

A primary line of defense in ensuring safe food is to obtain raw materials and ingredients from approved sources. The source is important because pathogenic microorganisms may be present in the breeding stock of animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown.

Additives

Additives are also a concern in raw materials. In excessive amounts or because of unapproved applications, additives may harm the consumer. Unintentional contaminants or residues—resulting from chemicals used in field soils, fertilizers, irrigation, and fishing waters, or hormones and drugs used in animal treatment—also may find their way into the food supply.

For this reason, raw materials and other ingredients must come from sources that comply with the laws and regulations regarding chemical additives and contaminants. **Methods to ensure compliance could include, among others, detailed product specifications, supplier warranties or letters of guarantee, verification programs to test supplier compliance, supplier visits, and documentation of restricted ingredient use.**

Evaluation & separation of raw materials

Raw materials that are damaged, spoiled, or otherwise unfit for use can contaminate foods, equipment, utensils, etc. To prevent this, procedures must be in place to evaluate products upon arrival at the facility and again prior to use. Separate areas must be designated for storing unusable materials awaiting disposition to keep them from being mistakenly used or contaminating other products.

Washing of raw materials

Pathogenic organisms and chemicals are often present on the exterior surfaces of raw ingredients (e.g., fruits and vegetables). While washing removes most contaminants, the ingredients could again become contaminated if non-potable water is used. In addition, toxic or undesirable residues could be left on the ingredients if the chemicals used for washing are unapproved or applied in excessive concentrations.

Root cause analysis

In food safety management, identifying and addressing the root causes of out-of-specification results, consumer complaints, and environmental monitoring failures is crucial for maintaining product integrity and consumer trust.

Unfortunately, many organizations fail to determine the root causes of these issues, leading to persistent problems that can compromise food safety. For instance, repeated complaints about contaminants or environmental monitoring results indicating pathogen presence, such as Listeria in facility drains, can signal underlying systemic issues that require thorough investigation.

Problem-solving tools

One significant barrier to effective root cause analysis is the lack of quality tools, such as the 5 Why's method or Fishbone diagrams. These tools are essential for systematically breaking down complex problems and identifying contributing factors. Without applying these techniques, organizations may overlook critical elements that lead to recurring issues.

For example, in a bakery where Listeria was found in a drain, the absence of a structured approach to problem-solving resulted in ineffective cleaning protocols. Only through the application of root cause analysis did the team discover that the wrong cleaning chemical was being used for pathogen control, highlighting the necessity of these quality tools in the food safety process.

Training deficiencies

The challenges associated with root cause analysis are often compounded by a lack of employee training in determining the root cause of issues. Many staff members may not have the necessary skills or knowledge to conduct effective investigations into food safety failures.

As a result, companies may experience repeat incidents, such as ongoing pathogen contamination or unresolved complaints, due to an inadequate understanding of how to analyze and rectify the underlying problems. Investing in training programs focusing on root cause analysis techniques can empower employees to identify and resolve issues proactively, ultimately leading to a safer food production environment.

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Real-world example

The implications of not addressing root causes can be severe. For instance, if Listeria contamination persists due to unresolved issues in cleaning protocols, it can lead to significant health risks for consumers and potential regulatory penalties for the organization.

In the bakery example, once staff received training on root cause analysis, they were able to implement the correct cleaning chemicals and procedures, effectively eliminating the contamination source. This illustrates how targeted training and the use of quality tools can lead to substantial improvements in food safety and operational effectiveness.

Supplier risk assessment

Understanding the distinction between low and high-risk ingredients is crucial for maintaining product safety and quality. Low-risk ingredients typically have a strong compliance history and pose minimal safety concerns, while high-risk ingredients may be susceptible to contamination, fraud, or other hazards.

For example, certain raw materials, such as honey, are classified as high risk due to their vulnerability to adulteration. Managing these risks involves rigorous vetting processes, including supplier audits, quality checks, and ongoing monitoring to meet safety standards consistently.

Risk assessment

One significant oversight in many food safety programs is the failure to incorporate supplier performance into risk assessments. A low-risk ingredient can escalate to a high-risk rating if it experiences out-of-specification results, recalls, or poor audit outcomes.

For instance, if a supplier consistently delivers products with quality issues or has a history of failed audits, the associated risks should be reassessed. Integrating supplier performance metrics into risk evaluations enables organizations to identify and address potential problems before they escalate, ensuring a safer food supply chain.

CAPA follow-up

Effective food safety management also requires diligent follow-up on Corrective and Preventive Actions (CAPAs) related to supplier issues. **When suppliers fail to meet specifications due to out-of-spec results, damaged products, or foreign material contamination, companies must have a structured process to investigate and resolve these concerns.**

Addressing these issues promptly through CAPAs not only helps prevent recurrence but also strengthens supplier relationships by demonstrating a commitment to quality and safety.

Risk management

Despite the importance of these practices, several challenges hinder effective supplier risk management. The sheer number of suppliers and ingredients can overwhelm organizations, making conducting thorough reviews and risk assessments difficult.

Limited staff resources and insufficient expertise in evaluating supplier risks can further complicate the process.

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For example, if a company encounters repeat issues with suppliers, such as damaged shipments or out-of-spec results, these problems may not receive the attention they deserve. Additionally, without sufficient focus on high-risk suppliers—like those providing honey—companies may overlook critical risks related to fraud and contamination.

Conclusion

Fostering a culture of continuous improvement and rigorous evaluation will ultimately lead to safer food products, greater consumer confidence, and a more resilient food supply chain. The changes in regulatory and enforcement programs are designed to improve the safety of the nation's food supply while making better use of limited agency resources.

These changes involved a shift from the command-and-control-based system, where the regulatory requirements are highly detailed and prescriptive, to a more performance-oriented system based on preventive controls. With this shift, companies will be afforded greater autonomy in decision-making. In return, they will take on greater responsibility for ensuring the safety of their products.

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