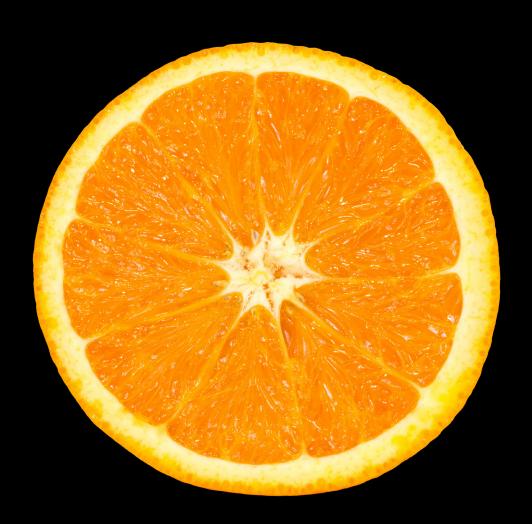
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Food safety management An enterprise and operational

level risk perspective

Background

The food and beverage industry continues to evolve at an increasingly rapid pace. New government regulations, along with expectations from consumers and stakeholders, compel food manufacturers, restaurants, and grocery retailers (referred to throughout as food companies, companies, or organizations) to sharpen their focus on food safety. These realities create an increased awareness of and sensitivity to foodborne illnesses and recalls. Meanwhile, many companies struggle to fully understand food safety risks presented by new and innovative—yet sometimes disruptive—operating models, and how to mitigate these potentially unfamiliar risks. The structure and management of food safety programs at food and beverage manufacturers, restaurants, and grocery retailers need to transform to navigate today's food safety landscape.

Companies can no longer rely on a single function to own quality and food safety because, simply put, food safety is an enterprise-level risk. They need to embrace the scientific, operational, and consumer perspectives of food safety if they want to identify and mitigate the myriad risks facing their organization. This paper describes how companies can embrace food safety as an enterprise-level operational risk and the key components needed in a food safety program.

Food safety transformational changes

There is little doubt that the food industry is undergoing transformational change, from consumers redefining food safety and increased government regulation and enforcement to evolving operational strategies and models required to maintain relevance in today's environment. Consumers are concerned not only about the immediate effects of food-borne illness or physical contamination—they also increasingly factor potential long-term effects of foods and ingredients into their buying decisions. Further, consumer trends bring focus to health and wellness, supply chain transparency, local sourcing, fresh and minimally processed foods, and social impact.

Meanwhile, the US Food and Drug Administration (FDA) recently finalized seven rules to implement the Food Safety Modernization Act (FSMA), which became law in 2011. FSMA represents the most significant change to US food safety regulations in over seven decades. Importantly, FSMA brings clear focus on the food supply chain, in-plant and in-transport food safety controls, verification of foreign suppliers' food safety programs, and provides the FDA with authority to pursue criminal prosecution of companies and company officers or employees.

As if changing consumer trends and increased government regulation weren't enough, each participant in the farm-to-fork continuum faces tremendous pressure to reduce costs and to achieve this in the face of consumers demanding more variety and customization. Food manufacturers often turn to outsourcing arrangements to maximize efficiencies and reduce costs, while restaurants and retailers must be quick to adapt to rapidly changing consumer tastes. Cost-reduction and efficiency-improvement initiatives have become a normal—and necessary—operational imperative.



An enterprise and operational risk food safety perspective

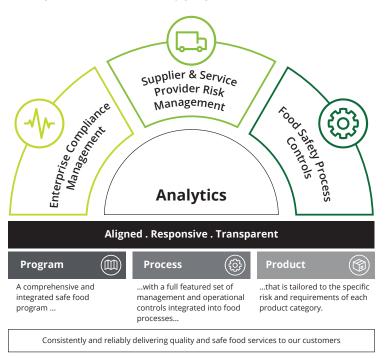
Moving from a purely scientific approach to one that incorporates scientific, operational, and consumer perspectives to identify and manage food safety risks is no small undertaking. Many companies understand the scientific basis for identifying microbiological, chemical, and physical hazards in their foods. Howerver, identifying food safety operational risks is more difficult because of the rapid external changes occurring in the industry. Operational risks go beyond regulatory compliance; they include customer, brand, supplier, and process risks posed to the organization.

Food safety should be championed and governed at the enterprise level to properly manage the operational risks to an organization. The food safety program should contain four components: enterprise risk and compliance management, supplier and service provider risk management, food safety process controls, and analytics to and monitor existing and emerging operational risks.

Operational risk based food safety program

Organizations should include four key components to develop and implement an enterprise-level operational food safety risk management program (see Figure 1).

Figure 1. Components of a food safety program



Enterprise compliance management

A risk and compliance program for food companies assesses the company's performance against regulatory requirements and internal standards. It should align with the company's enterprise compliance management program, which includes identifying, assessing, and mitigating compliance risk. When

identifying potential risks for the company, it's important to look across several factors to gain a holistic perspective on the state of food safety compliance. Figure 2 discusses the factors that should be assessed and how they relate to food safety compliance. The diagram illustrates that the food safety culture of the company is the central point for a food safety compliance program.

Figure 2. Food safety compliance framework components

Culture and strategy

Regulatory Communication, Escalation, measurement & measurement & reporting Risk assessments & regulatory change Policies and procedures

Position food safety compliance as a control function in key risk/reward and strategic decisions enterprise-wide

Create and design organizational structures and processes through which the board of directors, executive management, and Compliance leadership and professionals design, implement, maintain, assess, and oversee the food safety compliance program

Establish routine dialogue with critical regulatory stakeholders, both domestic and international, or with a regulatory communication group specifically set up within an organization

Establish the protocols and scope of services for who within the organization engages with regulators and how that engagement process works

Maintain an enterprisewide view of recent and planned food safety examination activities Establish communication protocols with all food safety compliance stakeholders

Facilitate timely communication in the wake of business and/or regulatory changes based on a proactive food safety communication plan

Update and facilitate compliance training, as needed, throughout the organization, based on a defined training plan Investigate issues raised by employees through "speaking up" programs and other channels; prioritize remediation; and assign accountability for the completion of remediation activities and

disciplinary requirements Establish a consistent set of standards by which food safety issues are identified, ranked, managed, and resolved Establish organizational food safety compliance reporting requirements, including defining and regular reporting of KRIs and KPIs

Assign standard compliance metrics that are tracked and managed over time

Establish reporting methodology to senior management and the board related to customer complaints Perform independent and periodic food safety monitoring and testing of compliance controls, based upon an established scope and cadence

Establish testing programs within the Compliance function that address both the design and operating effectiveness of key food safety compliance program elements and controls and is coordinated quality control (QA) and quality control (QC) testing

Identify processes for the ongoing monitoring of key food safety compliance risks and early warnings of breakdowns Develop a process and approach to appropriately manage regulatory changes (e.g., new laws, regulations, and regulatory guidance) procedures are in place, and that regulatory changes are identified and assigned/disseminated to appropriate parties within the applicable lines of business and exhaust containing a functions.

to appropriate parties within the applicable lines of business and shared services functions to update and refine other elements of the food safety compliance management program, as necessary

Establish and maintain library of the company's products and processes Establish and socialize business operating

Anchor policies, procedures, and related controls documentation to regulatory requirement and guidance

Define and document food safety compliance policies and standards, including the framework for identifying, assessing, controlling, measuring, and monitoring risks across the organization



Supplier and service provider risk management

A supplier and service provider risk management program is a foundational component for a food safety program. Suppliers and distributors provide a company with the inputs needed to produce the product and the means to send products to consumers or customers. Along the supply chain, there are many opportunities for food safety risks to occur. A supplier and service provider risk management program is needed to help identify and mitigate risks that may occur from suppliers or distributors. Figure 3 below highlights the five primary stages that should be included to mitigate those risks. As mentioned in the compliance framework and demonstrated in Figure 3, a supplier management program needs a foundation of food safety culture and governance.

Figure 3. Supplier and service provider risk management program

Foundational requirements for supplier & service provider risk management Company culture Governance & oversight Policies & standards Contract and on-board Ongoing Monitoring Terminate and off-board Processes & procedures Tools & technology Metrics & reporting

Operational requirements for effective supplier & service provider risk management

Food safety process controls

Food safety process controls must be in place at the operational level to ensure that the food being produced meets regulatory and organizational requirements and is safe for consumers. These controls are identified after a hazard analysis has been completed by the company to identify and assess the food safety risks associated with the specific ingredients used and the processes in which their food is prepared. Examples of food safety process controls are thermal processing with prescribed

cook time and temperature, foreign material identification, employee hygiene practices, product traceability, and allergen labeling and storage requirements.

Once controls are established there needs to be management oversight to verify that controls are being performed and are effective to mitigate the risks. Management can consider using technology to provide them with near real time visibility of risks and control effectiveness through dashboards and analytics.

Analytics

Analytics is the fourth component needed in an enterprise-level food safety program. Analytics bring data to life for company executives. It provides quantitative results that show how each of the other food safety components—compliance, supplier and service provider risk management, and food safety process controls—are performing across the organization. Analytics can provide insight into an organization's food safety program across several risk domains to help executives make real-time decisions using unbiased and quantified information (see Figure 4).

Figure 4. Risk sensing domains

Risk domain		Description
	Brand/reputation	Consumer sentiment that can influence company perception and value
Q	Macro/external	Factors outside the organization that can impact business operations
	Third-party	Vendors in the supply chain who can present unanticipated risks
	Fraud/counterfeit	Manipulation of product or business integrity, such as vendor collusion, adulteration, or copying
	Operational execution	Areas to improve efficiency or effectiveness of controls in operational processes
	Safety and quality	Vulnerabilities influencing operations, merchandising, withdrawals, and recalls
<u> </u>	Regulatory	New or emerging global and local regulations that can influence the product life cycle

An aligned, responsive, and transparent food safety program

An enterprise-level food safety program that contains the four program components and is aligned, responsive, and transparent allows it to be agile to both internal and external pressures and proactively identify and manage risks.

Alignment

Having a food safety program aligned to a company's business strategy and objectives assists in helping food safety be a cornerstone of the organization's mission. Food safety initiatives, including those to identify and mitigate new operational risks, should receive the necessary budgets, focus, and resources when the work is aligned to the overall objectives of the organization. Additionally, food safety can be incorporated

into other company initiatives that impact food safety or provide management of known operational risks.

Responsive

A responsive food safety program is essential if a company is to efficiently and effectively respond to market forces that impact the food and beverage industry. By having an enterprise-level food safety program, organizations can more quickly analyze and assess performance and make changes to the food safety program to mitigate risks or respond to market forces. Companies need to be responsive to a variety of market forces including supply chain disruptions, new product launches, consumer preferences, government regulations, and food safety control measures.

Transparency

Transparency across the enterprise is a vital necessity to identify food safety operational risks proactively. When executive leadership is involved with the food safety program, they have timely visibility into how the organization and its extended enterprise are performing against food safety requirements. They should have visibility into suppliers and the risk profile presented by the specific food supplied and the supplier. Visibility into distribution and logistics providers employed to move the product throughout the supply chain should also be afforded. The opportunity to review and understand food safety performance in the extended enterprise can allow the company to understand the potential for a food safety failure and develop mitigation plans before an event occurs.



About us

Deloitte Risk and Financial Advisory offers insights to help clients transition to an enterprise-level food safety program and develop and implement the critical elements. We've been where you are—in the fields, on manufacturing plant floors, in restaurant kitchens, in backrooms and delis of grocery stores, on trucks, and in warehouses and cold storages. We know your business and the challenges you face.

Deloitte Risk and Financial Advisory has a portfolio of capabilities, services, and technologies designed to help your company consistently deliver safe food to consumers.

These include:

- Deep subject matter specialists in diverse areas of food and beverage operations, including food safety, supply chain, quality, research and development, and regulations
- Industry-leading field examination processes and people to execute multidimensional field reviews of suppliers and operational facilities
- Technology solutions that provide executives with dashboards to view how the company and its extended enterprise are performing against food safety standards

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