

Regulatory Navigation Offerings

Leavitt Partners, a firm founded by former U.S. Health and Human Services Secretary Michael O. Leavitt, brings together high-level regulatory and food-safety experts to help you navigate the changing U.S. food-safety system. We bring knowledge, experience, and a network of global relationships that drive positive change.

Landscape

Lawmakers, regulators, consumers and the media are more focused on food safety than ever before. Changing consumption patterns, global sourcing, large outbreaks of foodborne illness, evolving food-safety science, and the identification of new risks all contribute to the shifting food-safety landscape.

Several outbreaks of foodborne illness in recent years have exposed new risks and put food safety in the spotlight. The science of food safety is continually evolving: new laboratory tests, improvements in genetic testing, and a greater fidelity of epidemiology have resulted in better capacity to detect and identify foodborne pathogens, and to link illnesses with specific food products.

The signing of the Food Safety Modernization Act (FSMA) by the U.S. President in January 2011 is the most sweeping overhaul of the food-safety system in the United States since the Food, Drug, and Cosmetic Act of 1938. The new legislation expands the authority of the U.S. Food and Drug Administration (FDA), and places new requirements on growers, manufacturers, processors, importers, and retailers whether domestic or foreign if they are putting FDA regulated foods into interstate commerce in the U.S.. The requirements in the new legislation set minimum standards for food safety with a heavy focus on prevention. To maintain their positions, industry leaders will seek solutions to manage the implementation of the FSMA consistently across their enterprise and industry, and to build in best food safety practices.

Our Past Experience

Leavitt Partners has worked with the full spectrum of the food industry from large multinational companies to small domestic firms who manufacture and process food as well as food service, retail, and technology companies to assist with navigating the regulatory environment. The Leavitt Partners team brings a range of regulatory and public health expertise. Our team brings insight and expertise gained during years of experience at the Department of Health and Human Services, Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and Environmental Protection Agency (EPA). In addition, we bring years of experience and expertise in health promotion, nutrition, and infectious disease medicine. Our combination of regulatory, public health, and medical experience enables us to bring a unique perspective to today's food safety challenges.

Do you have challenges knowing how to balance resources with the changing regulatory environment, pending new regulations and the increasing need to focus on food safety and quality. We specialize in working with companies to navigate these dynamic and challenging issues with a focus on balancing safety, quality and compliance in an environment of limited resources. Our regulatory and food safety experience at Leavitt Partners can assist your firm in navigating the continually evolving food safety landscape. Understanding the impact and implications of new laws and regulations that are resulting from the Food Safety Modernization Act and the current pressures on the food safety system will put your company in a position to proactively respond and establish themselves as an industry leader.

FSMA Gap Analysis

Leavitt Partners provides an array of assessment services to improve your company's safety, compliance, and efficiency through an analysis of gaps between current practices and new requirements. This is done in the context of working closely with the QA or Food Safety team as an interactive process.

Strategic Planning

Leavitt Partners can keep you up-to-date with the latest policies, rules and regulations coming out of Washington. In addition, our prior regulatory experience puts us in a unique position to interpret information and assess the unique impact on your company.

Information & Interpretation

Leavitt Partners can assist you with evaluating the current environment in relation to the risks associated with your business. This includes predicting the future impact, and prioritizing internal resources to strategically position your company to seamlessly navigate the changing food safety landscape. By engaging with our group we can help you balance food safety priorities based on risk, continued quality of product and the need to be compliant with new regulatory requirements.

Examples of Leavitt Partners services in this area include:

- Develop white papers on the impact of legislation on your company
- Provide insight to the company leadership on how to set priorities around change
- Provide presentations and training for employees
- Work directly with the food safety and quality team to put a practical perspective on the interpretation of regulatory requirements

Problem Resolution

When problems do occur, Leavitt Partners can assist you in developing a strategy, preparing documents, and engaging with regulators.

Examples of Leavitt Partners services in this area include:

- Assist your firm in conducting and documenting a root cause analysis following a problem
- Convene a group of experts to brainstorm solutions
- Assist with meeting and documenting requirements to get off of an Im-

Our Fees

Leavitt Partners can operate under retainer or project, payment structures. Due to the unique nature of each engagement, fees will be determined on a case by case basis.