FSMA Makes A Difference

Inteligistics

It's Time to Connect the Food Safety Dots

After nearly 5 years of discussion the Food Safety Modernization Act is becoming law on October 31, 2015. The FDA now has the full authority to make a difference. The first of seven new rules, the preventive controls rules, is a food safety game changer. Your current HACCP plan is no longer the core to your food safety plan.

The new mandated food safety rules require companies who operate FDA registered facilitates to use a new framework called HARPC or the Hazard Analysis Risk-Based Preventive Controls. Your company's hazard analysis needs to discuss if there are any known or reasonably foreseeable biological, chemical or physical hazards or any hazard that could be introduced for economic gain. So the defining of what is a foreseeable hazard and what is not becomes mission critical to the business enterprise.

Your company needs to have a much more science based and operational based plan. Your original plan focused on what was known to be a hazard, for example water quality. HARPC now requires one to analyze all the things that could affect the quality of the water, i.e. what are the water sources, are those sources tested before use, if they are put into a holding tank what other sources could be mixed in, could someone intentionally add in an agent that alters the water quality for economic gain, how secure is your water from outside threats? The purpose of your analysis is to determine if there is a hazard, what the risk is, and then define what the preventive controls are. This becomes part of an updated FSMA food safety plan.

The new preventive controls rule focus is on determining the probability of any contamination and assessing the severity of the illness or injury it could cause. The FDA wants the facility to address how the food is being supplied and processed, allergens, ingredients, equipment and how their intended use can affect potential hazards. The HARPC plan needs to be comprehensive and address environmental pathogens, temperature, humidity and other environmental monitoring and controls. For example, those ready-to-eat foods are particularly vulnerable to pathogens before they are packaged or foods that are washed before being packaged.

Additionally, your company will need to evaluate your supply chain, suppliers, and have a recall plan that can track back the tainted products to their sources. Verification of every step in the plan is key. Your company needs to be prepared to show documentation and your company must be able to prove that any of your controls are working effectively. This documentation and reporting will require extensive effort. Most companies do not have a food safety plan built into their information systems or ERP system.

As part of FSMA, FDA can access and copy records from domestic and foreign persons who manufacture, process, pack, transport, distribute, receive, hold, or import food (excluding farms and restaurants). This requires that your company needs to maintain a system of records for your operations for your own use and also that FDA can access as they required.

Doing a gap analysis that compares where you are with where you need to be by the enforcement date, for large companies September 2016, may be an urgent matter. The sooner the food safety dots can be documented and connected the better position your company will be.

Ask Inteligistics and their food safety experts for conducting a gap analysis as an initial step in becoming compliant with the FSMA preventive controls rules.

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