FSMA AND YOUR BUSINESS

KNOWLEDGE BRIEF

FSMA Hazard Analysis

The most important component in the new food safety regulations under FSMA is the requirement for a detailed *hazard analysis* of every step in the manufacturing process of human and animal food. That sounds simple, but it's not. In fact, conducting a hazard analysis is probably Priority Number 1 for food manufacturers and processors.

Read more about what a hazard analysis is all about here:

What Is a Hazard?

A proper hazard analysis will identify biological, chemical or physical agents present in the manufacturing or processing facility that have the potential to cause illness or injury. The standard for identifying these hazards has two components: those that are readily know, and those are known "reasonably foreseeable."

What that term means is very broad: reasonably foreseeable hazards may be naturally occurring, or they may be inherent to the product (i.e., controlled temperature); or they could be based on historical knowledge of foodborne illnesses, or from past recall data, from global information related to source of material, or from scientific information.

But that's not all. Hazard analyses also must cover the raw materials and other ingredients going into a product. These would include hazards that may be present (or created) in each step of the production process, and also could include hazards that may adversely affect the product's end user (i.e., customer or consumer). Environmental hazards must be considered when the product is exposed to the environment after processing; i.e., during the time before an item is wrapped or packaged.

Chemicals used within production facilities also fall under the hazard analysis protocol. Any chemicals that have direct or indirect contact with the food being produced, or the item's ingredients, or any surfaces where the food may have contact are included. Examples would be boiler water additives, release agents, lubricants and other maintenance chemicals, and cleaning and sanitizing materials.

Are Hazard Analysis Records Required?

A production facility's hazard analysis must be documented, with all sources of information listed. The document must be updated as needed and be accessible at any time for FDA inspectors, who will review the program, point out weak or undocumented procedures, and call upon subject matters experts if/when there are questions or concerns about the analysis.

What Else is Required?

Adhering to the new law's emphasis on prevention of food contamination will require manufacturers and suppliers to implement and maintain detailed documentation of steps they are following to prevent problems arising from the hazards from occurring. According to the FDA, preventative controls include

- **Management oversight of food safety** Preventative controls under FSMA become a management priority, with penalties for preventable lapses in food safety protocols.
- **Monitoring**: These are procedures designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include actual temperature values.
- **Corrective actions and corrections**: Corrections are steps taken to timely identify and correct a minor, isolated problems that occur during food production. Such corrective actions must be documented.
- **Verification**: These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

The FDA advises that product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. As an example, environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.

Is There Anything Else?

Yes. Under FSMA, food producers must create and maintain a food safety plan which, among other requirements, calls for the implementation of a detailed recall plan in the event of a food contamination.

When Does a Hazard Analysis Need to be Done?

Now. This week, this month. The analysis as the first or foundational document upon which a company's preventative controls and overall food safety plan is based. Think of it this way: a problem can't be solved or addressed until you know what the problem is.

Is There Help Available?

Yes. As FSMA's various requirements and details have been released, food manufacturers and suppliers are beginning to take action to insure compliance with the new regulations. In the area of MRO chemicals, including lubricants, CRC Industries is offering helpful guidance on how companies can manage their materials according to FSMA rules. Find out more here.