10 FREQUENTLY ASKED QUESTIONS ABOUT THE FOOD SAFETY MODERNIZATION ACT

The Food Safety Modernization Act (FSMA), created in 2011 by the Food and Drug Administration (FDA), is not new news to the food processing industry. However, because the required dates of compliance were years away from the time FSMA was created in 2011, the implementation of FSMA has seemed like a distant to-do. That is no longer the case.

Read on for 10 frequently asked questions about FSMA and the Preventive Controls for Human Food rule.

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1 What is FSMA, and what is the Preventive Controls for Human Food rule?

Created by the FDA, FSMA was signed into law on Jan. 4, 2011 and is one of the largest food safety laws created in more than 70 years. Its goal is to ensure the U.S. food supply is safe by encouraging a preventive – rather than reactive – approach to contamination.

FSMA's Preventive Controls for Human Food rule is the product of the FDA's outreach to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia and other stakeholders. The rule highlights four key requirements that food manufacturing facilities must meet to be compliant with the FDA.

2 What are the four key requirements of FSMA's Preventive Controls for Human Food rule, and what is the deadline for all adjustments to be made?

Facilities must establish and implement a food safety system that includes an analysis of hazards and risk based preventive controls. A written food safety plan is required and must cover: (a) hazard analysis, (b) risk based preventive controls, (c) oversight and management of preventive controls including monitoring, corrective actions and (d) verification that the preventive controls are working. The written food safety plan must address a Hazard Analysis and Risk Based Preventive Controls (HARPC) approach, rather than the Hazard Analysis and Critical Control Points (HACCP) approach that many facilities have used for years.

Depending on the type of food business in question, the deadlines for compliance with FSMA are as follows:

- Very small businesses averaging less than $1 million per year in annual sales of human food: September 2018
- Business subject to the Pasteurized Milk Ordinance: September 2018
- Small business with fewer than 500 full-time employees: September 2017
- All other businesses: September 2016

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3 What types of facilities are exempt from having to shift their approach from HACCP to HARPC as part of adjusting for FSMA?

There are six types of food facilities that are exempt from shifting their approach from HACCP to HARPC to comply with the final FSMA rule:

- Food companies under the exclusive jurisdiction of the U.S. Department of Agriculture
- Companies that are subject to FDA's new Standards for Produce Safety authorities
- Facilities that are subject to and comply with FDA's seafood and juice HACCP regulations
- Low acid and acidified canned food processors
- Companies defined as "small" or "very small" businesses
- Companies with a previous 3-year average product value of less than $500,000

4 What is the difference between HACCP and HARPC?

HACCP is a global standard that was originally developed to ensure built-in quality and food safety. It evolved as an effective, efficient and comprehensive food safety management approach. The system addresses food safety through the analysis and control of biological, chemical and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. The seven principles of HACCP include: (a) conduct a hazard analysis, (b) identify critical control points, (c) set critical limits, (d) establish monitoring actions, (e) determine corrective actions, (f) develop verification procedures, and (g) institute a record-keeping system.

HARPC is not a global standard but applies to almost all U.S. food processing facilities. It is an updated U.S. standard that was incorporated into FSMA in 2012. The process requires identification and prevention of all reasonably foreseeable food safety hazards – whether naturally occurring or unintentionally introduced into the facility. The seven requirements of HARPC include: (a) identify hazards, (b) include risk based preventive controls, (c) monitor effectiveness, (d) set corrective actions, (e) verify effectiveness, (f) manage recordkeeping and documentation, and (g) reanalysis every three years.

5 Can an existing HACCP plan be used with modifications to adjust for HARPC?

Certainly – a current HACCP program can be adjusted for HARPC with the help of a Preventive Control Qualified Individual. In fact, moving to HARPC from HACCP will be an easier shift than starting from scratch. The key adjustments that you would need to focus on include identifying risk based preventive controls for determined hazards, which should be expanded to include both naturally occurring and unintentionally introduced hazards.

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6 Which methodology should I use to analyze risks at my facility as part of the HARPC approach?

You should review the potential hazards – both seen and unseen – that could impact your facility to determine the risks that you should analyze for your plan. The potential hazards have expanded under HARPC in comparison to HACCP and include:

- Biological, chemical, physical and radiological hazards
- Natural toxins, pesticides, drug residues, decomposition, parasites, allergens and unapproved food and color additives
- Naturally occurring hazards or unintentionally introduced hazards
- Intentionally introduced hazards (including acts of terrorism)

From a pest management point of view, you should be analyzing the risks of what could encourage pests to enter your facility, such as doors left open or incoming product shipments.

7 How often should Integrated Pest Management (IPM) and written food safety plans be reviewed?

IPM plans should be reviewed on an annual basis with your pest management provider to ensure your program remains as effective as possible. Written food safety plans that follow the HARPC approach and comply with the FSMA rule should be reanalyzed whenever there is a significant change at the facility that might increase a known hazard or introduce a new one, and every three years (if no other significant changes occur).

8 What is most critical for audit success?

Documentation of every single action at your facility related to food safety – from potential risks to planned corrective actions to verification that the corrective action is effective – is essential for audit success. This stringent food safety documentation includes IPM documentation as well, as the pest control portion of your audit can amount to 20 percent of your total score. For tips delivered to your inbox that will help you prepare for your next audit, visit www.myauditprep.com and register today.

9 Do I need to make sure my suppliers are compliant as well?

If the supplier is located in the United States, they are covered under the same FSMA rule and should meet the mandated food safety requirements. This will help ensure both you and your suppliers are meeting high quality levels. If the supplier is not located in the U.S., the requirements under FSMA do not apply to them in the same manner since the FDA will not audit them; however, you should still ensure those international suppliers meet food safety requirements as if they were a U.S. entity so they meet your quality standards.

10 Will this new rule under FSMA improve safety of the food supply in general?

This is one of the most in-depth food safety laws created in recent years, and it covers every aspect of the food industry. It should make the U.S. food supply safer going forward.

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