



The Best in Pests™

10 FREQUENTLY ASKED QUESTIONS ABOUT THE FOOD SAFETY MODERNIZATION ACT

The [FDA Food Safety Modernization Act](#), or FSMA, was signed into law on January 4, 2011 and gave the Food and Drug Administration (FDA) new authority to regulate the U.S. food supply to better protect public health. Now that nearly all of the [required dates of compliance](#) for FSMA have passed, you should be confident that your food or beverage processing facility meets FSMA standards. But are you confident in how your pest control program supports your FSMA compliance?

Read on for 10 frequently asked questions about the FSMA's [Preventive Controls for Human Food rule](#), third-party audits and Integrated Pest Management (IPM).



ABOUT FSMA

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

Congress enacted FSMA in response to dramatic changes in the global food system and our understanding of foodborne illnesses. 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 and 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 FSMA.

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What are the key requirements of FSMA's Preventive Controls for Human Food rule?

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:

- ◆ Hazard analysis
- ◆ Risk-based preventive controls
- ◆ Oversight and management of preventive controls, including monitoring, corrective actions and verification that the preventive controls are working
- ◆ Supply chain program
- ◆ Recall plan

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.

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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



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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:

- ◆ Conduct a hazard analysis
- ◆ Identify critical control points
- ◆ Set critical limits
- ◆ Establish monitoring actions
- ◆ Determine corrective actions
- ◆ Develop verification procedures
- ◆ Institute a recordkeeping 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:

- ◆ Identify hazards
- ◆ Include risk-based preventive controls
- ◆ Monitor effectiveness
- ◆ Set corrective action
- ◆ Verify effectiveness
- ◆ Manage recordkeeping and documentation
- ◆ Reanalysis every three years



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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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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



HOW FSMA CAN AFFECT YOUR PEST CONTROL AND FACILITY OPERATIONS

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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 (such as change in process, change in product being produced, etc.), and every three years (if no other significant changes occur).
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What is most critical for facility audit success?

Complete documentation of every single action at your facility related to food safety is essential for audit success, from potential risks to planned corrective actions to verification that the corrective action is effective. This comprehensive food safety documentation should include IPM documentation since the pest control portion of your audit can count for up to 20 percent of your total score. For tips that will help you prepare for your next audit, download our free [Audit Preparation Guide](#) today.

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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.

Foreign producers of food or food ingredients imported to the U.S. must comply with a different portion of the FSMA program called the Foreign Supplier Verification Program (FSVP) and are still subject to FDA inspections. Orkin recommends that you still ensure that your international suppliers meet food safety requirements as if they were a U.S. entity so they meet your quality standards.

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How has FSMA improved safety of the food supply in general?

As one of the most in-depth food safety laws created in recent history, the law provides the FDA with new enforcement authorities designed to achieve higher rates of compliance in every aspect of the food industry with prevention- and risk-based food safety standards to better respond to and help contain problems when they do occur. Having a legislative mandate to require comprehensive, science-based preventive controls across the food supply will help strengthen the food safety system and make the food supply safer going forward.

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