carolina farm stewardship association

Local Food Safety Collaborative

FSMA FAQs: What are the requirements of HARPC and SCP under FSMA?

1. My human food business doesn't fit any HARPC exception. What are the requirements?

Hazard Analysis and Risk-based Preventive Controls (HARPC) in general are your business' plan and efforts to identify and address food safety risks—including pathogens, chemicals, toxins, unapproved additives, allergens or physical hazards such as glass or metal fragments—that might reasonably affect the foods you make or handle. HARPC under the PC Rule requires you to have a food safety plan that includes seven specific elements for every single food you produce.

i. Identification of food safety hazards: For every food, understand and document the relevant contamination risks, and the best steps to prevent those hazards.
ii. Preventive controls: For every food, implement practices that best prevent and minimize the identified hazards.
iii. Monitoring: Run checks to make sure that your preventive controls and food safety plan are actually being applied, and do so often enough to catch problems.
iv. Corrective actions: You must have a written plan that you follow when you do find evidence of a food safety problem that includes finding the cause and fixing it.
v. Recall program: You must have a recall plan and be ready to implement it should you put potentially products into the supply chain that are contaminated, mislabeled, or otherwise in violation of food safety rules.
vi. Verification: Your plan must include actions to assess that preventive controls and corrective actions are actually working to prevent contamination.
vii. Reanalysis: You must repeat the analysis of your hazards and preventive controls at least every three years, or more often if you make changes in your food processing or handling program or learn of a new threat.

Each of these elements of your HARPC program must be documented extensively, including the food safety plan itself, the procedures for carrying out the various steps of the plan, and that the procedures are being executed. All of these documents are subject to review in a facility inspection under FSMA.

NOTE: Facilities that are ***covered by existing FDA rules for thermally processed low-acid canned foods are exempt*** from HARPC and SCP with respect to ***microbial hazards***. These facilities still must have HARPC programs to address chemicals, toxins, unapproved additives, allergens or physical hazards.

2. What are the SCP requirements?

You must establish a Supply Chain Program (SCP) if your hazard analysis identifies a safety risk in any food product or ingredient coming into your facility that your suppliers need to address before you receive that food. So the SCP requirement would not apply if your facility applies a kill step to the foods you receive or the products that you make using them. However, if you are making ready-to-eat foods using raw produce, such as fresh cut fruit or coleslaw, your SCP must include verification that the farms that grew the raw produce and any distributors in between followed food safety practices to minimize contamination risk.

If you are required to have an SCP for a food or foods you make or handle, you can only use raw materials or ingredients obtained from 'approved suppliers' that you have verified are applying appropriate hazard controls. It is your responsibility to verify those suppliers through onsite audits, including third-party audits; sampling and testing of the raw material or ingredients; reviewing the supplier's food safety records; or by other activities, depending on the risk associated with the food. If the food coming into your facility poses a significant risk of causing serious illness, you can only receive the food if the supplier has had an audit, and in some cases it must be at least an annual audit.

Continued

NOTE: ***You are allowed to receive products from 'qualified exempt'[1] farms or other facilities even if they do not have an audit***, but those establishments must provide you written assurance:

- once per year that they are in fact qualified exempt; and
- every two years that they know they are subject to the Food, Drug and Cosmetic Act's prohibition on introducing adulterated food into commerce.

This document is not legal advice and is for educational purposes only. It has not been approved by the FDA.

[1] For more information about Qualified Exempt farms and facilities, see the FSMA FAQ '***What Are the Special Rules for Qualified Exempt Facilities?***'