HACCP & HARPC: FSMA Food Safety Plans for Processors

In the previous article, **Overview of the Seven FSMA Rules**, [link back to this article] two food safety plans were noted that are woven into the rules (the third food safety plan – Food Defense, is not discussed here). If you are affected by the FSMA Preventative Controls rules, either for Human Food or Animal Food, or both, perhaps you are trying to understand the food safety plan you are required to develop and implement. Read on to learn more about HACCP and HARPC and the FSMA food safety plans for processors.

HACCP

Hazard Analysis Critical Control Point (HACCP) is the globally recognized food safety management system (listed in the **Codex Alimentarius**) and has been used in United States commercial food production and processing since the late 1970s. [link http://www.fao.org/docrep/005/y1579e/y1579e03.htm]

HACCP is currently mandatory for juice, fish and seafood, and USDA inspected beef, pork and poultry processing facilities, and voluntarily implemented or encouraged in other food processing segments, such as Grade A Fluid Milk production.

HACCP is a food safety management system that manages the risk of food hazards contaminating a food product. Generally speaking, where critical hazards are identified in food processing facilities, science based, critical control limits are established to prevent or reduce the possibility of a hazard.

HACCP is in no way a substitute for any regulations and sanitation, pest control, food handling, or other practices that govern a facility. HACCP plans are often used in conjunction with these regulations and practices.

HACCP Summary

A simplified summary of the 7 principles of HACCP plan development follows. For detailed information and guidance in developing a HACCP plan, read the **FDA HACCP Principles and Application Guidelines**.

[link https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm]

- The HACCP team must analyze the food production process from start to the point of distribution, plus intended consumers.

- Identify all known biological, chemical or physical hazards that are likely to cause injury or illness if not controlled. Reasonably foreseeable hazards do not need to be considered.

- Evaluate the hazards to determine the critical ones and establish critical (minimum and maximum) limits and procedures to control to acceptable levels. Not all hazards can be prevented but where possible, procedures should address prevention measures.

- Establish monitoring procedures and documentation to ensure the critical limit is consistently met and procedures for when they are not met.

- Establish corrective action procedures and documentation when critical limits are not met.
- Establish verification procedures and activities. Verification intends to confirm the plan is still based on well founded science, properly functioning and followed to control hazards.
- Establish record keeping and documentation procedures for plan implementation.

Which FSMA rule requires a HACCP Plan?

- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (Foreign Supplier)

Foreign food suppliers importing any human and animal food into the United States are required to have written food safety plans. Because HACCP is the globally recognized food safety management system, this was the food safety plan FSMA chose for foreign importers.

HARPC

The new Hazard Analysis and Risk-based Preventative Controls (HARPC) is the FSMA food safety plan required for human and animal food processing facilities. This is a proactive and preventative control approach to food safety for processed animal and human food. It is science-based *and* risk-based, and applied throughout the processing, packing and holding chain of registered facilities. HARPC includes hazard analysis and preventative controls components.

HARPC Summary

A detailed summary of the HARPC food safety plan follows. This summary applies to both the Human Food rule and the Animal Food rule, with the exception of the Supply Chain Programs (see below).

For more detailed information, see the **FDA Preventative Controls for Human Food Regulation Guidance Summary, [link** https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm] the **FSMA Preventative Controls for Human Food Rule. [link** https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf] or the **FSMA Preventative Controls for Food for Animals Rule. [link** https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf

- ## **Hazard Analysis**

The HARPC food safety plan utilizes a broader hazard identification and analysis approach than HACCP. In addition to biological, chemical and physical hazards, HARPC includes radiological hazards (not included in HACCP) as a subset of chemical hazards. This addition is consistent with the HACCP Codex Alimentarius definition of chemical hazards.

HARPC also takes hazard analysis a step further. When analyzing the facility's processes, the Preventative Control Qualified Individual (PCQI) or team, must also consider known as well as reasonably foreseeable hazards, whether they are naturally occurring, unintentionally introduced or intentionally introduced to harm the food supply for economic gain.

For every hazard identified (not just the critical ones), a preventative control must be written and implemented by the facility.

- ## **Preventative Controls**

Food supply hazards can exist in other areas, as well. These additional types of preventative controls must be addressed in HARPC: Food Allergen Controls, Process Controls, Sanitation Controls and Other Controls. Each of

these controls address a specific aspect of the facility's manufacturing process.

Additional HARPC Components

Along with the hazard analysis and preventative controls building blocks of the HARPC plan, the FSMA rules require additional components to fully demonstrate the facility's activities to protect the food supply chain. Differences in Supply Chain Programs for Human Food and Animal Food are discussed. This is the only instance where Human Food and Animal Food HARPC criteria differ.

- ## **Oversight & Management of Preventative Controls**

Facilities must develop a written plan to confirm the controls are controlling the identified hazards. Oversight and management plans must include: monitoring, corrective actions, verification that corrective actions are followed and verifying the preventative controls are (still) scientifically valid and relevant to the manufacturing process.

- ## **<u>Human Food</u> Supply Chain Programs**

Human Food facilities must develop supply chain programs under specific conditions. If during the hazard analysis process, it is determined that a customer *or* another entity following the customer, will address the hazard through their process, the facility does not have to control the hazard. Two conditions apply to this scenario: 1) the facility must disclose in writing that the product hasn't been processed to control the identified hazard, and 2) receive written assurance from the customer or other entity that they will process to control that identified hazard. Other conditions may apply in addition to these mentioned above.

- ## **<u>Animal Food</u> Supply Chains**

A covered Human Food facility that creates, and donates or sells a by-product that will be used for animal food, does not need to implement additional preventative controls IF they are only holding (applying no further processing) the by-product. But, preventative controls may be needed to prevent contamination while in their possession.

A covered Human Food facility that processes the by-product for animal food use, must be comply with either the Human Food or Animal food cGMPs. Additionally, if the facility is required to have a Human Food HARPC plan, they must include the Animal Food processing in the hazard analysis. If no hazards requiring preventative controls are found, the facility must document the hazard analysis and results.

- ## **Recall Plan**

A written recall plan is required for every product a facility produces, that has a hazard that requires a preventative control. Procedures for notifying consignees and the public, and disposing of the recalled product(s) must be included.

Which FSMA rules require a HARPC Plan?

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventative Controls for Human Food)
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Preventative Controls for Animal Food)

What Does This Mean For You?

This is a detailed summary of HACCP and HARPC: FSMA food safety plans for processors. So, what does this mean for you? This is not the place to give an absolute answer, but, here is some general guidance:

- If you are a foreign food importer, expect to need a HACCP plan.

- If you are United States based facility processing Human or Animal food, and you are large enough to meet the FSMA business size requirements, you must have a written HARPC food safety plan. If you already have a HACCP plan, that's great, but it is probably not enough. Confirm whether it needs to be expanded into a HARPC plan.

- If you are a Human Food facility processing a by-product for Animal Food, you must include that process in your HARPC hazard analysis.