

# Comparing HACCP and HARPC

## What is the difference between the HACCP and HARPC?

The United States Congress signed the Food Safety Modernization Act (FSMA) in 2011 and the Food and Drug Administration (FDA) is mandated to implement the FSMA's new food safety regulations.

FSMA's proposed rules are preventative. With the globalization of the food supply chain and constantly emerging new food safety risks, the food industry is forced to take proactive steps to minimize and/or prevent potential for contamination of food and thus reduce food recalls across the food supply chain.

Under the FSMA Act, the FDA requires the food industry to implement comprehensive, science-based preventive controls across the food supply chain. This means that all food facilities that fall under the FSMA Act must conduct **Hazard Analysis and Risk-Based Preventive Controls (HARPC)** and establish science-based preventive control measures to reduce the risk of food contamination.

Therefore, the food industry should:

- Understand how the risk-based preventive control rules compare to HACCP principles, and,
- Establish process controls in order to achieve and maintain compliance with the new FSMA law for preventing risk of food contamination.



The Hazard Analysis and Critical Control Point (HACCP) system and the current Good Manufacturing Practices (cGMP) are primarily designed to ensure that food is manufactured, processed, packaged and stored in sanitary conditions to prevent post-process contamination in order to ensure that the food is safe, wholesome, and without visible quality deterioration.

The HARPC plan under FSMA has a similar concept, but the approach is somewhat different from cGMP and HACCP, as HARPC will enforce preventive controls to identify potential risks or threats to the food supply and to implement appropriate corrective actions proactively to prevent contamination. The FDA prescribes science-based standards for conducting hazard analyses, and implementing and documenting preventive controls.

FSMA proposes a “qualified individual “or a “team of qualified individuals” from a facility to understand the significant food safety hazards and put in place preventive controls to minimize the risk of hazards. The HARPC system requires food manufacturing facilities to identify and implement science or risk-based preventive controls, rather than critical control points (CCPs) as required by the conventional HACCP system. Therefore, the establishment of critical limits may not be required under the HARPC. The validity of preventive controls for minimizing the significant food risks should be backed up by scientific data or authentic scientific literature. A HACCP plan is not mandatory but the FSMA HARPC is mandated by law under the FSMA Act.

## What hazards should be identified for HARPC?

- 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).

### What examples of types of preventive Controls are listed in FSMA for the HARPC provision?

- Sanitation procedures at food surface contact points.
- Sanitation of utensils and equipment.
- Environmental monitoring program (for pathogen controls).
- Staff hygiene training.
- Food allergen control program.
- Recall plan.
- Current Good Manufacturing Practices (cGMPs).
- Supplier verification activities.



### Who is exempt from HARPC?

The following categories are exempted from the HARPC plan requirement:

- Facilities under USDA jurisdiction handling, processing, and shipping meat, poultry, eggs, etc.
- Operations under the FDA's Seafood and Juice HACCP regulations.
- Facilities subject to the FDA's new standards for Produce Safety Authorities. This exemption applies to farms, cooperatives, growers, harvesters and other companies handling raw fresh fruits and vegetables.
- Low acid and acidified canned food processors.
- Facilities defined as “small” or “very small” businesses.
- Facilities with a previous 3-year average product value or revenue of less than \$500,000.
- Facilities that mainly produce food for animals, store raw agricultural commodities other than fruits and vegetables intended for further processing, or facilities that store packaged food not exposed to the environment for potential cross-contamination.
- Facilities that are mainly engaged in manufacturing, processing, packing or holding that are considered to be low risk operations, such as shelling and hulling of almonds.
- Retail food establishments, restaurants, and farms.

### Who needs HARPC plan?

Any facility that manufactures, processes, packs, distributes, receives, holds or imports food must develop a HARPC plan for compliance with the FSMA HARPC compliance.

Except as exempted above, all facilities subjected to the FDA's Bioterrorism Facility Establishment registration, both in the United States and abroad, that are producing food products for distribution in the United States must

develop and implement a HARPC plan that identifies risks “known or reasonably foreseeable” for each type of food subject to the regulation. The preventive controls should be adequate to “significantly minimize or prevent” identified hazards so that the food is safe. The facility must provide a HARPC plan to the FDA upon receiving an oral or written request.

### **When was the HARPC plan implemented?**

FSMA HARPC was made into law on July 4, 2012. However, the FDA issued a proposed rule implementing the hazard analysis and risk-based preventive control provisions of the FSMA act on January 2013.

### **How frequently does the HARPC need to be updated and submitted to the FDA?**

The FDA requires that a facility updates its HARPC plan every 3 years or whenever there is a significant change in the processing facility that may increase a potential hazard or introduce a new hazard. Additionally, the FDA under the FSMA statute may require an updated plan based on unintentional or new hazards associated with biological, chemical, radiological or terrorist threats that may occur at a food facility that manufactures, processes, packs or holds food intended for human consumption.

### **What consequences can the FDA impose if no HARPC plan is in place or the plan is inadequate?**

If a facility mandated to develop a HARPC plan does not create a plan or if the FDA inspector determines that a HARPC plan is inadequate to address threats, the FDA can:

- Issue a public warning letter and/or an import alert for a foreign supplier, effectively banning imports from such a foreign supplier. Food products from a foreign facility or supplier that is placed on the import alert would be detained at US ports on arrival, thereby effectively barring it from entering into US commerce until the FDA reviews and approves an updated HARPC plan.
- Criminally charge a corporation or the person in charge of a facility for failing to meet HARPC compliance.
- Suspend the facility's food facility registration, thus preventing the facility from distributing food in the US until the FDA approves the updated plan and corrective actions. This would take place if food from a non-compliant facility is found to pose a significant food safety risk.

### **What type of scientific evidence is required under FSMA to validate process control?**

The FDA may accept established and proven process controls such as a pH level of less than 4.6 or a water activity of less than 0.85 or a cooking temperature of 165 deg. to validate the elimination of certain pathogens.

New studies would be required for new or novel processes and there is no scientific data or literature available to validate the effectiveness of process controls at mitigating hazards.

For more information on HARPC and HACCP contact us at [1-877-663-1160](tel:1-877-663-1160) for a project manager in your area or send a request for additional information at [www.pjrfsi.com](http://www.pjrfsi.com). ♦

