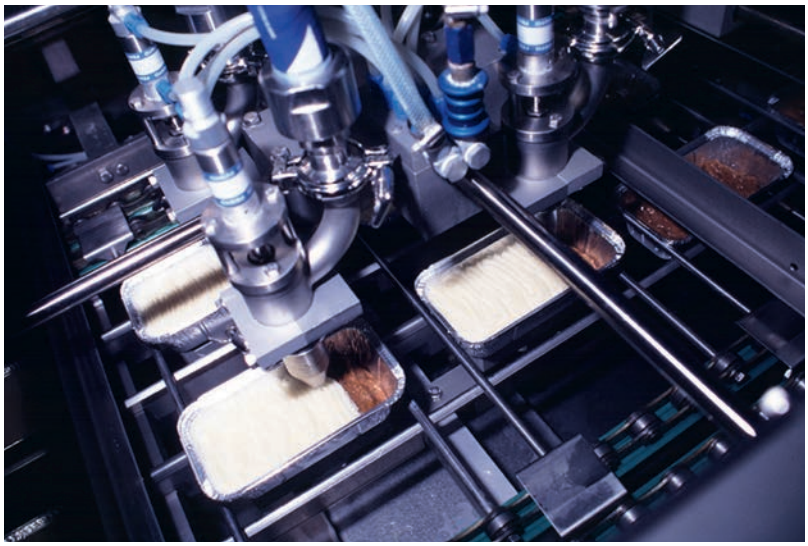
White Paper

HACCP Versus HARPC – What's the Difference?



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1 Introduction: HACCP Vs HARPC – What's the Difference?

Hazard Analysis and Critical Control Points (HACCP) and Hazard Analysis and Risk-based Preventive Controls (HARPC) are often discussed interchangeably in food-processing circles. However, if you ask most food processing professionals to explain the differences between the two, the answer may not come so easily. While HACCP is a well-known global standard, HARPC is relatively new.

This white paper takes a thorough look at each food safety standard and explains their similarities and differences, as well as the key steps food companies must take as they prepare to transition from HACCP to HARPC.

2 Food Safety Modernization Act (FSMA)

Every year, as many as 600 million people (or almost 1 in 10) in the world fall ill after consuming contaminated food, according to the World Health Organization's (WHO) first ever estimates of the global burden of foodborne diseases in 2015[1]. Foodborne illness outbreaks have triggered recent food safety legislation, including the Food Safety Modernization Act (FSMA) which was signed into United States (US) law in January 2011 and represents the first major reform of food safety laws in more than 70 years. To ensure the US food supply is safe, the FSMA shifts the Food and Drug Administration's (FDA) focus from responding to contamination to preventing it from occurring in the first place.

Foreign body in glass jar

By allowing the FDA to regulate through enforcement the prevention of food safety problems before rather than after they occur, the law is having a dramatic impact on food processing facilities. In particular, the Preventive Controls for Human Foods final rule significantly changes the way food processing companies document their food safety systems, as the traditional approach of using HACCP transitions to the new HARPC. Dates for compliance with the new preventive controls final rule are staggered, based on the size of the business. For example, large companies were required to be in compliance on September 19th 2016, while small companies (those with fewer than 500 full-time equivalent employees) were required to be in compliance on September 18th 2017. Very small companies (businesses averaging less than $1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale) are required to be in compliance on September 17th 2018[2].

Before we look at HARPC and its requirements in more detail, let us first focus on HACCP.

3 Hazard Analysis and Critical Control Points (HACCP)

Hazard Analysis and Critical Control Points (HACCP) is a systematic approach to the identification, evaluation and control of food safety hazards. It was conceptualized in the late 1950s and early 1960s by a team of engineers and scientists from National Aeronautics and Space Administration (NASA), the Pillsbury Company, and the Army's Natick Research Labs as a way of ensuring the safety of astronauts' food.

Since then, HACCP's evolution has been continual and resulted in a comprehensive food safety management system (FSMS). Pillsbury publicly presented the HACCP concept at the 1971 National Conference on Food Protection, and in 1974 the FDA incorporated its concepts into its low-acid and acidified-food regulations.

[1] http://www.who.int/mediacentre/news/releases/2015/foodborne-disease-estimates/en/
[2] https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

By the end of the 1980s, McDonald's started requiring its suppliers to adhere to HACCP to ensure the safety of food served in its restaurants. Shortly afterwards, other large companies followed suit. In 1989, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), published the first official HACCP document, standardizing the practice and presenting the seven principles of HACCP (listed below). Four years' later, the HACCP system was adopted by the Codex Alimentarius Commission.

HACCP requires a multidisciplinary team for implementation and is based on the following seven principles:

3.1 Conduct a Hazard Analysis

Food companies must list the steps in their manufacturing process and identify where significant hazards are likely to occur. A hazard is defined as any biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Once hazards have been identified and evaluated, the HACCP team must identify critical control points (CCPs).

3.2 Determine the Critical Control Points (CCPs)

A CCP is a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. A CCP may control more than one food safety hazard or, in some cases, more than one CCP may be needed to control a single hazard. The number of CCPs required depends on the processing steps and the control needed to ensure food safety.

3.3 Establish Critical Limits

A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP.

3.4 Establish Monitoring Procedures

Monitoring procedures must be established for the measurement of the critical limit at each CCP. These should describe how the measurement will be taken, when it will be taken, who is responsible for the measurement, and how frequently it will be taken during production.

3.5 Establish Corrective Actions

Corrective actions are the procedures that must be taken when monitoring indicates that a particular CCP is not under control and a deviation from an established critical limit has occurred. The HACCP team must identify the steps that will be taken to prevent potentially-hazardous food from entering the food chain, along with the steps necessary to correct the process. This includes identification of the problem and the steps taken to ensure it will not occur again.

3.6 Establish Verification Procedures

Verification is defined as any activities, apart from monitoring, which confirm the HACCP system is working effectively. Activities may include, for example, auditing of CCPs, instrument calibration and product testing.

3.7 Establish Record-keeping and Documentation Procedures

For the successful implementation of HACCP-based procedures, appropriate documentation and written records must be kept and be available to show that critical limits have been met and the system is in control.

4 Hazard Analysis and Risk-based Preventive Controls (HARPC)

Unlike HACCP, Hazard Analysis and Risk-based Preventive Controls (HARPC) is not a global standard, but an updated US standard incorporated into the FSMA on July 4, 2012. It applies to almost all food processing facilities, both in the US and abroad, who produce food products for distribution in the US.

Sec. 103 of the Food Safety Modernization Act describes HARPC in the following way:

> *"The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice."* [3]

Under the FSMA, the FDA has a legislative mandate to require a qualified individual or team of qualified individuals from virtually every food facility to understand the food safety and adulteration risks associated with their foods and processes, and implement science-based preventive control measures to reduce the risk of food contamination.

Each facility must have a written food safety plan and perform the following seven tasks for HARPC compliance:

4.1 Identify Hazards

The "HA**"** in HARPC stands for "Hazard Analysis" and addresses the main purpose of the law, which is to identify hazards that may arise due to the specific foods or ingredients in the food or the various processing, manufacturing, packing and holding steps applied to the foods. Once identified, the company must develop a plan to minimize or prevent the hazards from arising. During the first HARPC step, food companies must evaluate the product and processing for the risks of:

- 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)

The final bullet point includes all aspects of a food company's facilities (e.g. the physical plant and security measures to prevent potential bioterrorism events), personnel screening and controls, the entire supply chain of a facility's food ingredients (raw materials, packaging, dyes, labels, etc.), and the finished foods received, delivered and shipped. Companies must create a written analysis of the above hazards and include both an identification of the risks, as well as an analysis of the risks as they relate to (or could relate to) the facility and the foods or food ingredients it handles.

[3] https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC103

4.2 Develop and Implement Risk-based Preventive Controls

The "RPC" in HARPC stands for "Risk-based Preventive Controls." Companies are required to develop and implement a series of risk-based controls at the points of the manufacturing process where the identified hazards must be prevented or minimized to ensure food safety. The facility must designate control measures at each point to ensure the greatest level of risk prevention or mitigation is achieved by normal operation of that manufacturing, processing, packing or storage step.

The following types of preventive controls are listed:

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

4.3 Monitor the Controls' Effectiveness

Food companies are required to establish and implement monitoring programs to verify that the preventive controls are working. However, unlike with a HACCP system, not all controls will have specific limits.

4.4 Outline Corrective Actions

Any deviations from the risk-based preventive controls and control measures in a properly-designed HARPC system must be identified, evaluated and corrected. The corrective action steps include:

- Recognition of weak spots in the controls
- Recognition of ineffective controls
- Recognition of new hazards
- Performing vital steps to reduce the chance of a recurrence
- Assessing the processed food for safety
- Prevention of contaminated food from entering commerce

Facility owners and operators are required to identify and fix "out of control" processing steps and evaluate processed foods for safety and adulteration risks.

4.5 Verify the Effectiveness of the Controls

Food facilities are required to design and implement verification steps to ensure their HARPC plans (the hazard identification and analysis, preventive controls and control measures, monitoring and corrective actions) are operating correctly to prevent or minimize food safety and adulteration hazards. This step is designed to verify that:

- The selected preventive controls are sufficient
- Monitoring is occurring correctly as defined in the plan
- Suitable corrective actions are taken
- Potential food and food processing hazards are minimized
- Periodic reviews are conducted at suitable intervals so the HARPC plan remains pertinent and includes new and emerging risks and hazards

4.6 Maintain Written Records

One significant development under HARPC is its new requirements relating to records and documentation that have become mandatory for food facilities. Previously, the FDA could only require food companies to keep records that enabled food to be traced through the supply chain "one up/one down". Now, HARPC stipulates that records and documents related to food hazards and process control systems are established and kept for no less than two years to cover the following HARPC steps:

- The monitoring of the preventive controls
- All cases of deviation or processing nonconformity that could affect food safety
- Testing results and other verification steps aimed at ensuring preventive controls are effectively reducing or preventing hazards
- All cases where corrective actions were required
- Demonstrating the effectiveness of a food facility's preventive controls and corrective actions

4.7 Reanalyze the HARPC Plan

Food facilities must assess their food safety plans regularly and update them whenever there is a significant change at the processing facility that may increase a potential hazard or introduce a new one, or every three years if no other significant changes occur.

Additionally, HARPC requires facilities to carry out a new hazard analysis and implement any new, necessary preventive controls before operational changes occur.

Any changes must be documented in the company's HARPC records. If no changes are required after the HARPC system is reanalyzed, the company must document the grounds for that decision. Facility owners, operators and agents may also have to reanalyze their HARPC plans at any time if the Department of Homeland Security identifies new biological, chemical, radiological or terrorist threats.

5 Additional Information on HARPC

5.1 Who is exempt from HARPC?

The following categories are exempted from the HARPC plan requirement:

- Facilities under the United States Department of Agriculture (USDA) jurisdiction handling, processing, and shipping meat, poultry, pork and eggs
- Facilities subject to 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, but only as the regulatory controls govern and control certain aspects of microbiological contamination (e.g. botulism)
- Businesses defined as "small" or "very small" (exemption ceases by mid-September 2018)
- Facilities with a previous three-year average product value 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

5.2 Who needs a HARPC plan?

Aside from those facilities exempted above, all facilities subjected to the FDA's Bioterrorism Facility Establishment registration, both in the US and abroad, that are producing food products for distribution in the US 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 supply a HARPC plan to the FDA upon receiving a written or oral request.

5.3 Who is responsible for the HARPC plan?

The owner, operator, or agent in charge of a domestic or international food facility is required to develop an adequate HARPC plan for any facility that is subject to FDA food facility registration under The Bioterrorism Act. Failure to implement HARPC is defined by the FSMA as a "prohibited act" and will lead to criminal prosecution of the company and/or the owner, operator or agent in charge.

5.4 How often should you submit or update your HARPC plan?

The FDA requires that facilities update their HARPC plan every three years or whenever there is a substantial change in the processing facility that may increase a potential hazard or introduce a new one. Furthermore, the FDA may require an updated plan based on unintentional or new hazards associated with biological, chemical, radiological or terrorist threats that many occur at a food facility that manufactures, processes, packs or holds food intended for human consumption.

5.5 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 it is insufficient to address threats, the FDA can:

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

6 Conclusion

For all food supply chains, HARPC represents a substantial new regulatory requirement that must be taken seriously. HACCP and HARPC share more than just four letters, they are both food safety standards based on prevention, but they differ on execution.

The similarities between HACCP and HARPC include the requirement for conducting a hazard analysis, implementing controls, monitoring and corrective actions. However, as this white paper shows, HARPC's food safety plan requirements are more comprehensive than the traditional HACCP system. A HARPC hazard analysis, for example, includes more detailed hazard identification and evaluation. Unlike HACCP, it includes planning for potential terrorist acts and/or intentional adulteration and food fraud. A facility's HARPC plan should therefore include additional security, such as visitor access and control. Supplier and recall programs are also more formal with HARPC.

Additionally, the HARPC system requires food facilities to identify and implement science or risk-based preventive controls, rather than critical control points (CCPs) as required by the conventional HACCP system. As such, the establishment of critical limits may not be required under HARPC. A HARPC plan should not be considered as a replacement to the conventional HACCP plan, but as a necessary upgrade, and it is important food companies take time to educate themselves on the new regulatory requirements.

If facilities have an effective HARPC plan in place, they are also in compliance with HACCP. If, however, they currently function under HACCP guidelines, it is their responsibility to determine if they must comply with HARPC under FSMA.

7 Summary Table

An overview...	HACCP	HARPC
Where are the standards recognized?	HACCP is a global standard	HARPC is a US standard, applicable to certain FDA-regulated products
Who must comply?	HACCP is mandatory primarily for facilities processing juice and seafood, as well as USDA-regulated meat and poultry.	HARPC applies to almost all food processing facilities, including companies required to register with the FDA in accordance with the Bioterrorism Act. There are six categories of exemption to HARPC: • Companies covered under the juice and seafood HACCP rules • Companies exclusively regulated by the USDA, such as those that handle, process, and ship meat, poultry, and eggs • Companies subject to the FDA's Standards for Produce Safety Authorities, including farms, growers, and harvesters • Low-acid and acidified canned food processors • "Small" or "very small" businesses • Companies whose previous three-year average product value was less than $ 500,000
What hazards are considered?	HACCP covers chemical, biological and physical hazards.	HARPC covers chemical, biological and physical hazards, as well as radiological hazards, intentionally-introduced hazards (e.g. acts of terrorism), and unintentionally-introduced hazards.
How are the plans implemented?	HACCP focuses on critical control points (CCPs), which are points at which a control is required to prevent or reduce a food safety hazard. Hazard analyses are based on industry-wide documentation, and implementation relies on sanitation standard operating procedures (SSOPs).	For HARPC, a hazard analysis is only the first step. The rule also requires companies to develop science or risk-based preventive controls, validate that the controls work, and verify that they are implemented consistently. Each facility is responsible for performing and documenting its own research.
How often do you need to review and update your plan?	HACCP plans are reviewed once a year or whenever there is a significant change.	HARPC plans are reviewed once every three years or whenever there is a significant change.
What happens if you don't comply?	Noncompliance with HACCP most often results in fines and a plan for re-evaluation.	Noncompliance with HARPC can result in anywhere from a suspension of the facility's registration to criminal prosecution.

8 References

http://www.who.int/mediacentre/news/releases/2015/foodborne-disease-estimates/en/

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC103

http://blog.alchemysystems.com/four-key-stops-on-the-journey-from-haccp-to-harpc

https://safefoodalliance.com/newsletter/2015-05/what-is-the-difference-between-the-haccp-and-harpc/

https://www.harpc.com/

https://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2015/hazard-analysis-and-risk-based-preventive-controls-harpc-the-new-gmp-for-food-manufacturing/

http://www.pjrfsi.com/downloads/Comparing%20HACCP%20and%20HARPC.pdf

https://www.foodonline.com/doc/explaining-differences-between-haccp-and-harpc-0001

https://unithermfoodsystems.com/haccp-vs-harpc-answers-to-common-questions/

9 Recommended Reading

Further information can be found at:

The Organization for Machine Automation and Control (OMAC) – www.omac.org

Organisation Internationale de Métrologie Légale (OIML) – www.oiml.org

Fertigpackungsverordnung (FPVO) – www.bundesrecht.juris.de/bundesrecht/fertigpackv_1981/gesamt.pdf

German Federal Institute of Physics and Technology (PTB) – www.ptb.de

EHEDG – www.ehedg.org

GFSI – www.mygfsi.com

FSMA – www.fda.gov

BRC – www.brcglobalstandards.com/

IFS – www.ifs-certification.com/index.php/en/

FSSC 22000 – www.fssc22000.com/documents/home.xml?lang=en

SQF – www.sqfi.com/

Preventing Product Recalls – http://www.mt.com/pi-productrecalls

FSMA Final Requirements – http://www.mt.com/pi-fmsa

How to Prevent Foreign Body Contamination – http://www.mt.com/xray-preventforeignbodies

Principles of Due Diligence – http://www.mt.com/pi-duediligence

How Hygienically-designed Equipment can Reduce Operational Costs – http://www.mt.com/pi-hygienicdesign

Validation, Verification and Monitoring For Product Inspection Equipment – http://www.mt.com/pi-validation

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