



## Aligned Hazard Analysis Programs Food HACCP and PSM

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The ultimate responsibility for food safety lies with food service providers and their ability to develop and maintain effective food safety management systems. Currently, there is a shift in the emphasis of hazard analysis and preventive controls related to both process safety management (PSM) and Hazard Analysis and Critical Control Points (HACCP). This is of particular concern for the food industry, where many regulations include both EHS and food safety requirements.

Many food operations fall under both PSM and HACCP requirements. In general, PSM is bulk chemical-centric for food operations, while HACCP is food safety risk-centric for maintaining food purity. *(Common chemicals subject to both include anhydrous ammonia for cooling and chlorine for sanitation of product and processes. In addition, many large food processing types include process aids at levels under PSM.)*

Changing regulations and the increased emphasis on hazard analysis require the food industry to develop well-documented and managed programs that address both PSM and HACCP using common approaches:

- Better use of organizational resources
- Standard programs
- Training efficiency and effectiveness
- Shared knowledge and approaches
- More effective and aligned hazard analysis management

### About PSM

PSM is a key risk management practice that must be implemented for qualifying plants. PSM is covered in the recent Executive Order focused on modernization of high-risk sites and, as a result, is under greater scrutiny with regulator focus and recent events. While PSM is a highly visible requirement, it is currently not widely inspected and reviewed—though that may be changing. PSM generally entails a more event-driven inspection by interested parties other than the company. As a growing area of focus and concern, PSM will require plants to reassess and, potentially, update systems and operations to meet requirements.

### About HACCP

HACCP, on the other hand, is widely implemented for food processing and is expanding with high visibility. HACCP is the historic requirement providing the accepted food safety plan for some food industries. HACCP is rapidly being advanced with FSMA and GFSI-level requirements, but requirements have not been fully established based on FSMA rulemaking. The complexity of programs is rapidly increasing, while the level of food industry sectors is expanding to include all food contact, packaging, GRAS, and distribution and transportation companies.

## Hazard Analysis Methods

The hazard analysis methods under PSM and HACCP are similar but different:

- **Process Hazard Analysis (PHA)** is associated with high-risk chemicals or materials, and is required for compliance with PSM. A PHA is designed to protect people and the environment from specific hazards. PHA methods vary based on an organization's determination of the best method for their situation. These methods are directed to the overall process and operating condition by the process step. PHA focuses largely on equipment, instrumentation, utilities, human actions, and external factors that might impact the process. It involves an organized, systematic analysis of potential hazards to improve safety and reduce the potential consequences of those hazards.
- **Hazard Analysis and Preventive Control (HAPC)** is associated with food safety risk under Hazard Analysis and Risk-based Preventive Controls (HARPC) and is an aspect of HACCP. HAPC is a growing regulatory compliance requirement related to food safety plans (FDA and USDA) that focuses on process, equipment, contamination, procedures, and control points. HAPC involves an organized and systematic analysis of potential risks to food and food materials to improve the purity of food during processing/handling by reducing contamination.

PHA and HAPC are required for facilities, as determined by the regulations, and include the following common requirements:

- Develop preventive control plan
- Perform hazard analysis for foreseeable hazards (written)
- Conduct "what-if" scenarios, rating, and ranking
- Identify and implement preventive controls, as well as intentional hazards and controls

Under both PSM and HACCP, all plans and records may be subject to inspections. Failures to act can provide willful non-conformance or probable cause for expanded inspection.

## Additional Requirements

Companies subject to PSM and HACCP need to consider other related regulatory requirements, as well. This relationship in itself is key under GFSI.

- **Records**
  - Maintain evidence
  - Conduct development programs and hazard analysis adequately
  - Establish programs to ensure preventive controls
  - Conduct training
  - Validate and verify programs, completed forms
  - Record all key information relevant periods
- **Inspections**
  - PSM-level inspections can be part of incident follow-up or planned OSHA or NEP inspections; there is state registering of PSM inspections.
  - HACCP will be part of mandatory FDA inspections, by any qualified agency to FSMA, and under GFSI and customers as part of their supplier programs.
- **Cleanup and Catch-up**
  - Monitor effectiveness

- Establish corrective actions
- Verify programs and preventive controls
- Monitor and support SOPs/GMPs
- Diligently follow and record Management of Change (MOC)

In addition, hazardous materials and communication are key for both EHS and FDA, as well as areas like air quality, water quality, sanitation, and blood borne pathogen/bodily fluids.

### **The Right Resources**

A higher level of compliance requires plans to be reassessed and, subsequently, the resources to reassess them. For many, once programs are developed, they are put into “maintain” mode. Historical knowledge isn’t captured or is lost to turnover.

Beyond that, PSM and HACCP both require that “qualified individuals” develop and manage these systems. Qualified individuals include a designated lead with certain experience and qualifications, as outlined in the requirements. Availability of resources is almost always an issue, as maintaining systems with just one person is very difficult, especially given organizational change.

Keeping qualified resources at the proper certification is difficult. New employees are now typically required to provide both oversight and operational capability. The mix of education, work experience, and certification are all important. The growing approach is to maintain teams with alternates to supplement the leads and to provide coverage for all situations, including daily/weekly schedules. This is an area that must be continually monitored and subjected to corrective action.

### **Alignment Strategy**

The following tips will help to effectively align PSM and HACCP programs and strategies, and provide for efficient compliance with both regulatory programs:

- Establish plans to assess existing programs
- Apply continuous improvement (Plan-Do-Check-Act)
- Take inventory of qualified resources
- Align qualified personnel to PSM and HACCP teams
- Use a sub-team approach to ensure the necessary level of participation and backup
- Maintain multi-year strategy, planning, and training
- Establish a cleanup and catch-up approach for hazard analysis activities to move forward
- Use continuous improvement to maintain validated and verified programs