WHITE PAPER

HACCP Planning for Food Safety

REMCO PRODUCTS

The essentials of HACCP Planning.

Food processors across the country are addressing the ramifications of the 2011 Food Safety and Modernization Act (FSMA) that requires them to be registered with the FDA and routinely inspected for compliance with food safety practices. As part of the FSMA, the FDA released a proposed rule on preventive controls for human food that focuses on preventing problems that can cause foodborne illnesses. The rule has two major features: 1) new provisions requiring Hazard Analysis and Critical Control Points (HACCP), and 2) proposed revisions of Current Good Manufacturing Practice (CGMP) requirements under 21 CFR Part 110.

The HACCP food safety management system requires food processors to have a written safety plan or a "HACCP Plan" which begins by conducting a Hazard Analysis that identifies "Critical Control Points" or CCPs — those points, steps or procedures in food manufacturing process at which control can be applied and as a result, a food safety hazard can be prevented, eliminated or reduced to an acceptable level. Once CCPs are identified, food processors can then establish critical limits for each CCP, then continually monitor, take corrective actions where necessary, then validate and document that safe procedures are being followed. (1)

HACCP defined.

HACCP stands for "Hazard Analysis Critical Control Point." A HACCP Plan includes a series of procedures to control the process and sensitive points in the food chain, with the ultimate goal of producing consumer foods that are safe for consumers' health.

Developed in the 1960s by Pillsbury Company, the US Army Laboratories and NASA, HACCP is now a recognized international standard for safe food production. It is endorsed by the Food and Agricultural Organization (FAO), the World Health Organization (WHO), and in the United States by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). (2)

Understanding the seven HACCP principles.

Developing a proper HACCP Plan follows the seven principles as outlined by the United States Department of Agriculture or USDA: (3)

Principle 1: Conduct a Hazard Analysis.

- Plants determine the food safety hazards and identify the preventive measures the plant can apply to control these hazards.

Principle 2: Identify Critical Control Points.

- A critical control point (CCP) is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Principle 3: Establish Critical Limits for each Critical Control Point.

- A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level.

Principle 4: Establish Critical Control Point Monitoring Requirements.

- Monitoring activities are necessary to ensure that the process is under control at each critical control point. FSIS (USDA Food Safety Inspection Service) is requiring that each monitoring procedure and its frequency be listed in the HACCP Plan.

Principle 5: Establish Corrective Actions.

- These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP Plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Principle 6: Establish Record Keeping Procedures.

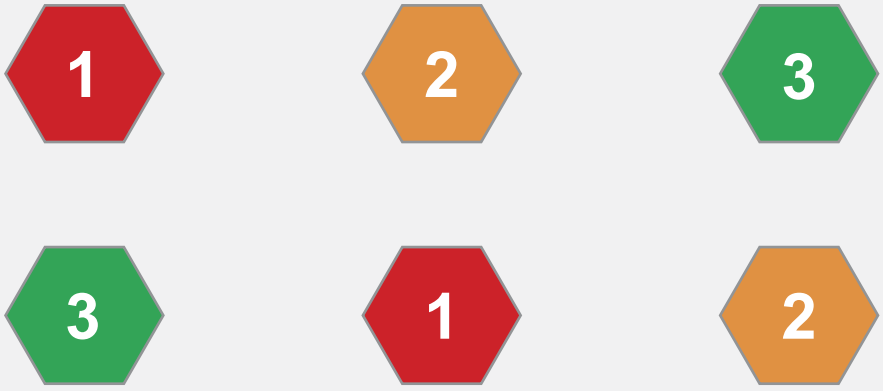
- The HACCP regulation requires that all plants maintain certain documents, including its Hazard Analysis and written HACCP Plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

Principle 7: Establish Procedures for Verifying the HACCP System is Working as Intended.

- Validation ensures that the plans do what they were designed to do; that is, they are successful in ensuring the production of safe product. Plants will be required to validate their own HACCP Plans. FSIS will not approve HACCP Plans in advance, but will review them for conformance with the final rule.
- Verification ensures the HACCP Plan is adequate, that is, working as intended. Verification procedures may include such activities as review of HACCP Plans, CCP records, critical limits and microbial sampling and analysis. FSIS is requiring that the HACCP plan include verification tasks to be performed by plant personnel. Verification tasks would also be performed by FSIS inspectors. Both FSIS and industry will undertake microbial testing as one of several verification activities at the occurrence of the identified food safety hazard.

Thinking through a HACCP Plan.

While there are many steps involved with developing a HACCP Plan, at its foundation is the fundamental thinking necessary to logically work through construction of the plan based on a facility's process. For instance, how does one step in the process lead to another and then another? Are there distinct steps in the process that are or should be maintained separately? The exercise to the right demonstrates this fundamental thinking.



Connect the shapes that correspond by number and color with one line. The lines may not cross.

Assemble your HACCP team.

With the governing principles of HACCP in hand, one can begin to develop a HACCP Plan. It's advised that key managers from the food processing organization assemble and collaborate in the development the HACCP Plan. Typical titles of those professionals who might be involved include:

- HACCP Coordinator
- Quality Assurance Manager
- Plant Operations Manager
- Engineering Manager
- Maintenance Manager
- Sanitation Manager and/or Supervisor
- Shipping & Receiving (Warehouse) Manager and/or Supervisor
- Line Supervisor and/or Machine Operator

Note: It's suggested that one person within an organization take responsibility for the development and long-term maintenance of the company's HACCP Plan. That person is usually the HACCP Coordinator. However, if an organization doesn't have a HACCP Coordinator, then the responsibility is often assigned to the Quality Manager or even the company's CEO.

In addition, a food processor might consider hiring an independent SQFI or federal-certified consultant to help with the development of and compliance to the HACCP Plan. It's advised that this third party consultant be certified at an auditor level by the FDA and/or sanctioned organization such as the Safe Quality Food Institute (SQFI), American Institute of Baking International (AIB) or NSF International.

Identify the products that will be covered by the HACCP Plan.

Many companies produce multiple product lines. For those companies, it's important that their HACCP Plans contain a Hazard Analysis for each product manufactured with the following information included:

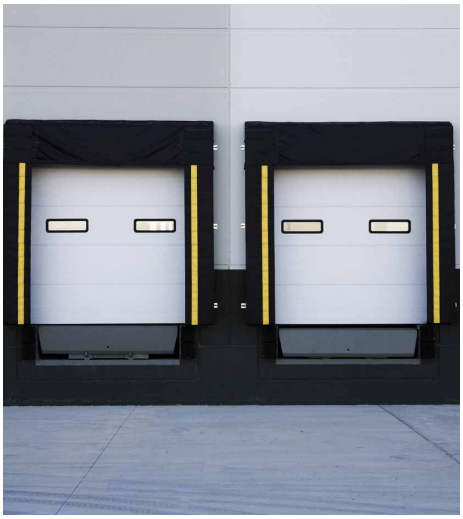
- Product name
- Product description
- Ingredients
- Processing methods
- Food safety factors
- Distribution methods
- Intended use
- Target consumer

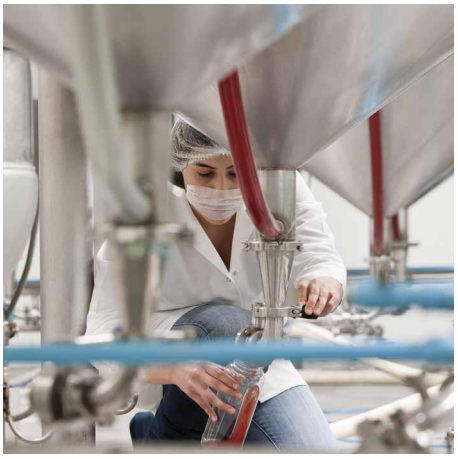
Suggestion: Once the Hazard Analysis has been compiled for each product, it's ideal to capture it in a visual form, e.g., a table or graph, to help in identifying commonalities, as well as areas of risk for cross-contamination or other hazards.

Visualize your process.

Once each product has been identified with food safety factors identified, a Process Workflow Chart can be developed to further illustrate each step of the process. From the time ingredients, packaging and other raw materials enter the facility to the final stages when the food products are packaged, labeled and shipped, every step in the process should be accounted for. Below is a simplified Process Workflow Chart provided as an example.

Illustration A:





Evaluate hazards and identify CCPs.

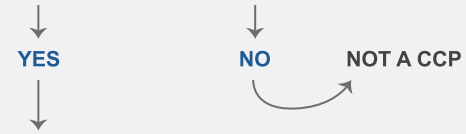
At a minimum, a HACCP Plan should identify and prioritize the hazards and their critical limits, and establish actions to eliminate, prevent or reduce the hazards. Using a Decision Matrix can be helpful tool in thinking through the various potential hazards within a food processing facility.

The Decision Matrix (see example Illustration B) begins by reviewing each step in the workflow process and the likelihood of hazards that could occur. Once a hazard is identified, then it must be evaluated whether or not it is a CCP. If a control measure is already in place to address the hazard, then the hazard is not a CCP. If a control is NOT in place to secure food safety, then it is a CCP and a control measure should be considered to reduce the hazard.

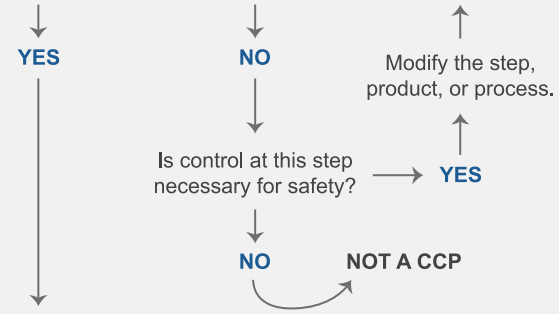
Illustration B: [4]

FDA example of a CCP Decision Tree

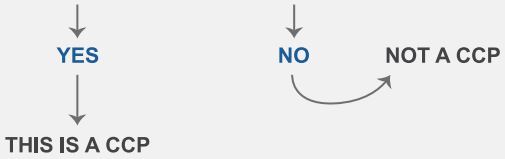
1) Does this step involve a hazard of sufficient likelihood of occurence and severity to warrant its control?



2) Does a control measure for the hazard exist at this step?



3) Is control at this step necessary to prevent, eliminate, or reduce the risk of the hazard to consumers?



Create a Hazard Analysis Worksheet.

In working through the Decision Matrix, one will discover that not all hazards are CCPs. This may occur because another step or action in the process negates the hazard, or there's already a control measure in place. In any case, the best way to evaluate the severity of each hazard is by working through a Hazard Analysis Worksheet.

Illustration C below is an excerpt of a typical Hazard Analysis Worksheet. At the

top of the worksheet are the key areas of analysis — starting with the ingredient/step in the process being evaluated through to the final determination of whether or not it is a CCP and its risk rating (1 through 5).

In Column 1, you will see three examples of items that might be evaluated: a Vegetative Ingredient, Pasteurization and Blending. Other items that might typically be included here are additional steps in the process, as well as points of contact with vendors, employees, tools, machines and packaging.

Illustration C:

List each ingredient & step in processing	Identify potential hazards for each ingredient & step	Indicate the hazards controlled for each ingredient & step	Does the potential hazard need to be controlled in the HACCP plan (not just this step)	Justification for answer (use severity decision matrix)	If answered "yes" what measures can be applied to reduce, prevent or eliminate hazard	Is this a CCP? If "yes" identify hazard and assign a number
Ingredient	**Biological: Vegetative & spore forming pathogens** Chemical: Physical:	B: None C: None P: None	**No**	Low likelihood; GMP & vendor certification programs are functioning and in place	Regular inspections of storage areas performed. Only approved vendors are used. QA inspects all ingredient shipments	**No** CCP:
Pasteurization	Biological: None Chemical: None Physical: None	**B: vegetative pathogens** C: None P: None	**Yes**	Medium likelihood, severity is high SQF 2, B=5	Pasteurization Cooking time & temperature chart and CCP log.	**Yes** CCP: **1 (B)** SQF 5 = CCP
Blending	Biological: None Chemical: None **Physical: Foreign material that can cause injury**	B: None C: None **P: Foreign material large enough to cause injury**	**Yes**	Medium likelihood, severity high SQF 2, A=3	A sifter screen is located at the bottom of the blender. Blender CCP Log	**Yes** CCP: **2 (P)** SQF 3 = CCP

Maintain your HACCP Plan.

Putting your HACCP Plan together is one thing. Monitoring its success is quite another. For this, a Critical Limits Monitoring Worksheet and Corrective Actions Worksheet can be helpful. (See Illustration D.) It is suggested that a HACCP Plan be reviewed at a minimum once every 3 to 6 months.

Illustration D:

Control Point	Specific Hazard	Critical Limits (Pass/Fail)	Monitoring Details			Corrective Action	Verification	Validation
			What	How & Who	Frequency			
Describe control point and indicate the #	Describe/ outline hazard clearly	Specify measureable limits that identify a pass and fail situation	**Define what is measured**	Define how measurements are taken, in detail, the equipment used, and identify the person(s) who will perform the monitoring	Identify how often measurements are taken	Describe actions taken when a failure occurs, in detail, from failure point to resolution	Is the HACCP system working? Specify the measurement or inspection procedure to be performed, equipment, and frequency	If the system is working, will it produce safe food? Outline testing results, studies and/or reputable reference materials, and all documents/ reports, proving "your" specific process.
Ex. CCP1: **Hot fill of jars and inversion w/hold time**	Ex. Presence of vegetative pathogens	Ex. Product fill temperature of ≥190°F	**Ex. Temp of product must be ≥190° F** **Immediate jar inversion** **Time held inverted must be ≥ 5 min.**	Ex. Personnel: HACCP trained production personnel (Ex. filler operator) will observe and record temperature and time, where required Equipment: in-line calibrated thermocouple and chart recorder at filler exit point, in addition to a hand-held calibrated thermometer Visual inspection of jars immediately inverted and then packed into cases in the inverted position to ensure holding time is met.	Ex. Continuous recording by thermocouple and chart recorder Batch product temp is verified at start, in hour increments, and at exit of each batch by machine operator with a calibrated hand-held thermometer and documented in log at observed times.	Ex. If the minimum temp is not reached the fill operation stops until the temperature returns to within acceptable limits. All jars filled since the last "good" check are tagged with a "QA HOLD" tag and are removed in a segregated location until they can be re-processed the same day during the same batch/ lot run.	Ex. Activity: Calibration check of thermometers will be checked (daily) by QA Personnel before start of production with an NIST certified standard. Equipment & Records: QA Lab instrumentation and calibration log	Ex. Activity: Customer complaints are monitored (daily) by QA Supervisor for any reports of illness. Records: QA Supervisor report & analysis of complaints
Corrective Action notes to record and be kept for reference:					1. Identify cause 2. Eliminate cause 3. Identify when CCP will be under control 4. Specify measures to be taken to prevent re-occurrence 5. Prove no deviating product enters commerce			

Note: Anytime anything new is introduced into a company's food process, (e.g., a new vendor, ingredient, machine, employee, process flow, equipment, tools, packaging, etc.), the HACCP Plan and its potential CCPs should be reevaluated. Proper documentation is also essential for HACCP compliance. This topic in itself is quite detailed and should be part of a company's HACCP food safety program. Check for other white papers to cover the elements of HACCP documentation.

Conclusion.

Developing a HACCP Plan takes teamwork, attention to detail, dedication and logical thinking. It also takes an ongoing commitment to keep the plan up-to-date and monitor its success. With a HACCP Coordinator assigned to the tasks, and the support of company management, a proper HACCP Plan can be integral to maintaining a company's food safety program and compliance with FDA regulations. For a more detailed understanding of FDA food safety regulations and HACCP planning, one might consider attaining HACCP certification. There are many training courses and resources available. The Food Safety and Inspection Service (FSIS) has published several resources to aid small producers in getting started with HACCP. This list of resources is available at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/small-and-very-small-plant-outreach/svsp-outreach

References:

[1] FDA, http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334115.htm

[2] University of Florida, EDIS, http://edis.ifas.ufl.edu/fs122

[3] FSIS, http://www.fsis.usda.gov/Oa/background/keyhaccp.htm

[4] FDA, http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#app-h; Appendix E and F.

[5] International HACCP Alliance, http://www.haccpalliance.org/sub/index.html

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