

HACCP Plan Requirements in a Retail Food Establishment

A HACCP Plan is an assemblage of operational analyses and procedures to control the factors that directly contribute to foodborne illness. Smoked meats, dried meats, Reduced Oxygen Packaging of food which is potentially hazardous and packaged juice to sell to other businesses are some of the processes for which a HACCP plan is required.

Reduced Oxygen Packaging includes:

- *Vacuum Packaging*, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;
- *Modified Atmosphere Packaging*, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food (Modified Atmosphere Packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen);
- *Controlled Atmosphere Packaging*, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, non-respiring food, and impermeable packaging material;
- *Cook-Chill Packaging*, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed and the bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or
- *Sous Vide Packaging*, in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

The HACCP plan includes:

1. A categorization of the types of potentially hazardous food (time/temperature control for safety food)
2. A flow diagram by specific food or category type;
3. A food employee and supervisory training plan;
4. A statement of standard operating procedures; and
5. Additional scientific data or other information

Categorization of the Types of Potentially Hazardous (Time/Temperature Control for Safety) Food

Potentially Hazardous Food (PHF) is the common term used to identify food that supports the growth of pathogens or has been implicated in foodborne disease outbreaks. Currently, the FDA has inferred a new term for this food – Time/Temperature Control for Safety. These are defined as a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation. This includes:

- an animal food that is raw or heat-treated;
- a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or
- garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and
- a food that because of the interaction of its aw and ph values is designated as product assessment required (PA) in Table A or B:

TABLE A. INTERACTION OF PH AND AW FOR CONTROL OF SPORES IN FOOD HEAT-TREATED TO DESTROY VEGETATIVE CELLS AND SUBSEQUENTLY PACKAGED				
Aw VALUES	pH VALUES			
	4.6 OR LESS	>4.6 – 5.6	> 5.6	
≤0.92	NON-PHF*/NON-TCS FOOD**	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	
>0.92 - .95	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	PA***	
>0.95	NON-PHF/NON-TCS FOOD	PA	PA	
* PHF MEANS POTENTIALLY HAZARDOUS FOOD ** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *** PA MEANS PRODUCT ASSESSMENT REQUIRED				
TABLE B. INTERACTION OF PH AND AW FOR CONTROL OF VEGETATIVE CELLS AND SPORES IN FOOD NOT HEAT-TREATED OR HEAT-TREATED BUT NOT PACKAGED				
Aw VALUES	<4.2	4.2 - 4.6	>4.6 - 5.0	>5.0
	NON-PHF*/ NON-TCS FOOD**	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD
0.88 - 0.90	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA***
>0.90 – 0.92	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA	PA
>.92	NON-PHF/ NON-TCS FOOD	PA	PA	PA
* PHF MEANS POTENTIALLY HAZARDOUS FOOD ** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *** PA MEANS PRODUCT ASSESSMENT REQUIRED				

The food that is identified as PHF/TCS requires controls during preparation and storage. It is these items for which HACCP plans are required.

Food that is NON-PHF does not require HACCP plans for special processing and is not listed in the categorization process. Food that qualifies as Non-Potentially Hazardous (Non-PHF/Non-TCS) is:

- an air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;
- a food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;
- a food that because of its ph or aw value, or interaction of aw and ph values, is designated as a non-phf/non-tcs food in table a or b of this definition;
- a food that is designated as product assessment required (pa) in table a or b of this definition and has undergone a product assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients, extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or a combination of intrinsic and extrinsic factors; or
- a food that does not support the growth or toxin formation of pathogenic microorganisms even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

Flow Diagram by Specific Food or Category Type

Identify critical control points and provide information on ingredients, materials, and equipment used in the preparation of that food and formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved. The flow diagram should be a step-by-step written guide of preparation from receiving ingredients from suppliers to storage of the product until removed from reduced oxygen packaging. These steps include receiving ingredients, storage of the ingredients, preparation steps, cooking, packaging, cooling, and additional storage until used. A Critical Control Point is always listed as a separate step in a flow diagram. A Critical Control Point (CCP) is defined as any point in a food preparation process at which loss of control might result in an unacceptable consumer health risk. CCPs are typically temperature control steps including refrigerated/frozen storage, cooking, and cooling.

Food Employee and Supervisory Training Plan

An integral component of a HACCP plan is a training program that addresses the food safety issues of concern. The training plan is addressed in the FDA manual "*Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments.*" The training component is used to educate employees about protecting products from contamination by biological, chemical, and physical food safety hazards; controlling bacterial growth that can result from temperature abuse; and maintaining equipment in a clean and sanitary manner. These training programs include proper hand washing, cleaning and sanitizing of food contact surfaces, and proper storage and use of toxic chemicals.

Statement of Standard Operating Procedures

The statement of standard operating procedures for the plan under consideration includes clearly identifying:

- Measures for cleaning & sanitizing;
- Controls for contaminants in production areas;
- Each critical control point;
- Critical limits for each critical control point;
- Method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge;
- Method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring each critical control point;
- Action to be taken by the person in charge if the critical limit for each critical control point is not met; and
- Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed

Many of these steps are tracked as part of the charts and logs developed and completed for the HACCP plan. The charts include the hazardous analysis chart, summary of critical control points chart, refrigerated/frozen storage monitoring log, cooking log, cooling log, and calibration log.

Additional Scientific Data or Other Information

Additional scientific data may be required to support the determination that food safety is not compromised by the proposal. This includes testing results from a laboratory for acidity of the food (pH) and water activity of food (A_w). When processes do not follow Sous Vide or Cook-Chill cooking, food packaged using a Reduce Oxygen Packaging method must be either a food that has a water activity of less than .92 or an acidity (pH) of less than 4.7. Three samples from three batches must be tested to determine a consistent recipe and outcome results. Once the three samples are tested and the results are approved by the department, Reduced Oxygen Packaging may begin.