



TENNESSEE DEPARTMENT OF AGRICULTURE

Division of Consumer & Industry Services

GUIDANCE FOR REQUESTING A VARIANCE

Retail Food Store Sanitation 0080-04-09

What is a Variance?

A “variance” is defined as a written document issued by the Department that authorizes a modification or waiver of one or more requirements of the Code. If in the opinion of the Department, a health hazard or nuisance will not result from employing the activities detailed within the modification or waiver a variance may be granted. The decision to grant or deny a variance request will be based on the best available science submitted by the applicant or sought out by the **Tennessee Variance Committee** at the time the decision is made.

When is a variance or HACCP plan required?

Some types of food or food processing will require a variance and an approved Hazard Analysis Critical Control Point (HACCP) Plan; while some food, food processes, and circumstances will require a HACCP Plan, but not a variance.

What is HACCP?

HACCP, as defined by the National Advisory Committee on Microbiological Criteria for Foods, consists of a seven-step process that a food producer or establishment operator can use to address hazards introduced or controlled by a process.

HACCP Principles are:

1. Conduct a food safety **HAZARD ANALYSIS**.
2. Identify **CRITICAL CONTROL POINTS**, also called “CCPs.”
3. Establish **CRITICAL LIMITS** for preventive measures.
4. Establish **MONITORING PROCEDURES** for control points.
5. Establish **CORRECTIVE ACTIONS**.
6. Establish an effective **RECORD KEEPING/DOCUMENTATION** system.
7. Establish **VERIFICATION PROCEDURES** to ensure the HACCP Plan is working.

What is a HACCP plan?

A **HACCP** plan is defined as a written document that delineates the formal procedures of following HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Contents of a HACCP Plan

The HACCP plan shall indicate:

1. A categorization of the types of Time/Temperature Control for Safety Foods (TCS) that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or other foods that are specified by the Department;
2. A flow diagram by specified food or category type identifying critical control points (CCP) and providing information on the following:

- 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.
3. Food employee and supervisory training plan that addresses the food safety issues of concern;
 4. A statement of standard operating procedures for the plan under consideration, including clearly identifying:
 - Each CCP
 - The critical limits for each CCP
 - The method and frequency for monitoring and controlling each CCP by the food employee designated by the person in charge (PIC)
 - The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCPs
 - Action to be taken by the PIC if the critical limits for each CCP are not met; and
 - Additional scientific data or other information as required by the Department in support of the determination that food safety will not be compromised by the proposal.

What types of processes require a HACCP Plan and NOT a variance?

1. TCS food that is packaged using a Reduced Oxygen Packaging (ROP) method and is maintained at 4°F or less and meets at least one of the following criteria:
 - Has a water activity (Aw) of 0.91 or less;
 - Has a pH of 4.6 or less;
 - Is a Meat or Poultry product cured at a Food Processing Plant regulated by the USDA using substances specified in 9 CFR 424.21, *Use of Food Ingredients and Sources or Radiation*, and is received in an intact package; or
 - Is a Food with a high level of competing organisms, such as raw Meat, raw Poultry, or raw vegetable.
2. Fish that is frozen before, during, and after packaging using a ROP method;
3. Food that is prepared and packaged using a cook-chill or sous vide method;
4. Specific cheeses that are packaged using a ROP method;

What types of food and/or methods require a variance?

Food establishments shall obtain a variance from the Department before:

1. Smoking food as a method of food preservation rather than a method of flavor enhancement;
2. Curing food;
3. Using food additives or adding components such as vinegar to address pH:
 - As a method of food preservation rather than as a method of flavor enhancement; or
 - To render a food so that it is not TCS
4. Packaging food using a ROP method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled
5. Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;

6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment;
7. Preparing food by another method that is determined by the Department to require a variance;
8. Sprouting seeds or beans; or
9. Certain raw or undercooked animal foods as described in section 0080-04-09-.03(6)).

How does my establishment apply for a variance?

The *Request for a Variance* application shall be submitted to the Tennessee Food Variance Committee. The committee includes a food scientist, representatives from industry, as well as state and local public health agencies appointed by the Department.

The applicant shall provide the following information with the application:

1. A statement of the proposed variance to Tennessee rule 0080-04-09 requirement citing the relevant Code section(s);
2. An analysis of the rationale for how the potential public health hazards addressed by the relevant Code will be alternatively addressed by the proposal; and
3. A HACCP Plan, if required, that includes the information relevant to the variance request.

When will I know if my variance has been approved?

The Variance Committee meets once a month (first Wednesday of each month) to review variance applications. You will receive written notice on the application within one week of the review.

Can I work under the variance before it has been approved?

NO, regulations must be followed as written until the firm receives written notice that the variance has been approved.

How will my inspector know that I have an approved variance?

A copy of the approved variance will kept on file with the department, but it is the firm's responsibility to maintain a copy and have it available when asked to provide it during an inspection.