



## GUIDANCE FOR REQUESTING A FOOD ESTABLISHMENT VARIANCE

### When is a variance required?

A variance is required when a food establishment would like to make a modification or waiver to one or more requirements of Hawaii Administrative Rules (HAR) 11-50 if, in the opinion of the Department of Health (DOH), a health hazard or nuisance will not result from the modification or waiver.

A variance is also required for a food establishment that conducts specialized processing methods, as noted in HAR 11-50-34(j). These specialized processes include:

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement
2. Curing food
3. Using food additives or adding components such as vinegar:
  - a. As a method of food preservation rather than as a method of flavor enhancement; or
  - b. To render a food so that it is not potentially hazardous
4. Packaging food using a reduced oxygen packaging method except where the growth of and toxin formation by *C. botulinum* and the growth of *L. 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 DOH to require a variance, i.e. jerky or drying processes
8. Sprouting seeds or beans

## What is HACCP?

HACCP or Hazard Analysis Critical Control Point is defined by the Food and Drug Administration (FDA) as a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

HACCP consists of 7 principles:

1. Conduct a food safety HAZARD ANALYSIS,
2. Identify CRITICAL CONTROL POINTS (CCP),
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 critical control point?

A critical control point (CCP) is any step at which factors can be controlled when this control is *essential* to prevent, eliminate, or reduce a food hazard to an acceptable level.

## What is a critical limit?

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 of occurrence of a food safety hazard.

## References for helping in the development your HACCP plan:

[https://edis.ifas.ufl.edu/topic\\_haccp](https://edis.ifas.ufl.edu/topic_haccp)

<http://smchealth.org/sites/default/files/users/ljoyner/HACCP%20Pages%201-6%20to%201-8.pdf>

For log templates: <http://sop.nfsmi.org/HACCPBasedSOPs.php>

## What are the requirements for submitting a variance request?

A completed variance application with fee;

A statement of the proposed variance of the rule requirement citing relevant rule section(s). Explain what you would like to do and the section of the law it affects;

An analysis or documentation that supports your claim that a hazard or nuisance will not be created if the variance is granted;

A HACCP plan for any of the specialized processing methods listed earlier (HAR 11-50-4(j)(2))

The HACCP plan shall indicate:

- a. The food product(s) subject to the HACCP plan;
- b. The food safety issues of concern (i.e. specific bacteria);
- c. A *flow diagram* for EACH product or product type, identifying EACH CCP and including:
  - i. Ingredients, materials, and equipment used in the preparation of product,
  - ii. Product recipes and detailed directions of how product is prepared,
- d. Training plan that addresses the food safety issues of concern;
- e. Identify and provide details for:
  - i. Each CCP,
  - ii. The critical limits for each CCP,
  - iii. How (method) and when (frequency) designated employee will monitor and control each CCP,
  - iv. How (method) and when (frequency) the supervisor will verify that the designated employee is following the procedures set in step iii,
  - v. Corrective actions by the supervisor if the critical limits for each CCP are not met,
  - vi. Records to be maintained by the person in charge;
- f. Any additional scientific data or other information to support that the food produced is safe

## EXAMPLE OF HACCP PLAN

**Food item:** Bottled coconut syrup, acidified

**Hazards:** *C. botulinum*, thermophilic bacteria

**Ingredients:**

Water

Sugar

Coconut

Ascorbic acid

Potassium sorbate

**Equipment:** Kettle, automatic filler

**Process:** Mix ingredients in kettle, heat to 250°F, cool, fill bottles.

**Training plan:** Acidified food processing class

**Verification Procedures:** Night shift supervisor will verify records at end of each operating day.

**Record maintenance:** Records maintained for 90 days.

**Flow diagram:**

