

GUIDANCE FOR REQUESTING A VARIANCE

North Carolina Rules Governing the Food Protection and Sanitation of Food Establishments

What is a *Variance*?

A “variance” is defined by the 2009 NC Food Code to mean a written document issued by the Regulatory Authority that authorizes a modification or waiver of one or more requirements of the Code, if in the opinion of the Regulatory Authority, a health hazard or nuisance will not result from employing the activities detailed within the modification or waiver. 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 **NC 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 “CCP’s”.
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 by the 2009 NC Food Code 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 and specifications shall indicate:

1. A categorization of the types of Potentially Hazardous Foods (Time/Temperature Control for Safety Foods) 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 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 critical control point (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 Regulatory Authority, supporting the determination that food safety is not compromised by the proposal.

What Types of Processes Require a HACCP Plan and NOT a Variance?

1. Potentially Hazardous Food (Time/Temperature Control for Safety 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 (A_w) 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;
5. Unpackaged juice prepared on the premises in a Food Establishment for service or sale that serves a Highly Susceptible Population.

What Types of Food and/or Methods Require a Variance?

Section 3-502.11 states that a Food Establishment shall obtain a variance from the Regulatory Authority as specified in Sections 8-103.10 and 8-103.11 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 potentially hazardous (Time/Temperature Control of Safety Food);
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 as specified under Section 3-502.12;
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 Regulatory Authority to require a variance;
8. Sprouting seeds or beans; or
9. Certain raw or undercooked animal foods as described in Paragraph 3-401.11(D).

How Does my Organization or Establishment Apply for a Variance?

The *Request for a Variance* application shall be submitted to the North Carolina Food Code Variance Committee. The committee includes a Food Scientist, as well as representatives from industry, 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 the NC Food Code requirement citing the relevant Code section(s);
2. An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Code will be alternatively addressed by the proposal; and
3. A HACCP Plan, if required as specified by Paragraph 8-201.13(A), that includes the information specified in Section 8-201.14 as it is relevant to the variance request

REQUEST FOR A VARIANCE

North Carolina Rules Governing the Food Protection and Sanitation of Food Establishments

Date: _____

1. Establishment/Organization Name: _____

2. Physical Address: _____

City: _____ State: _____ Zip: _____

3. Mailing Address (if different from above): _____

City: _____ State: _____ Zip: _____

4. If applying for multiple locations, please attach a list of facilities to this application.

5. Organization Contact Name: _____

6. Contact Telephone Number: () _____ Fax Number: () _____

7. Email Address: _____

8. Type of Variance Requested:

Note: All processes listed below require a Hazard Analysis Critical Control Point (HACCP) Plan submitted with the Variance Request.

- | | |
|---|--|
| <input type="checkbox"/> Smoking Food for Preservation | <input type="checkbox"/> Reduced Oxygen Packaging |
| <input type="checkbox"/> Acidification of Food for Preservation | <input type="checkbox"/> Custom Processing of Animals for Personal Use |
| <input type="checkbox"/> Molluscan Shellfish Life-Support Tank | <input type="checkbox"/> Preparing Food by Another Method* |
| <input type="checkbox"/> Sprouting Seeds or Beans | <input type="checkbox"/> Other [†] |
| <input type="checkbox"/> Curing Food | |

*If preparing food by another method that is determined by the Regulatory Authority to require a variance, please list the food and process with evidence specific to this process in the form of a peer-reviewed study(ies) or validated process.

[†]For other rule modification or waiver requests, please state the rule, reason for the request, and supporting documentation demonstrating why a health hazard or nuisance will not result from the modification or waiver.

Please submit application and supporting information to:

Food Protection Program/Variance Committee
Environmental Health Section
1632 Mail Service Center
Raleigh, NC 27699-1632

For questions, please contact (919) 707-5854.



North Carolina Public Health
Working for a healthier and safer North Carolina
Everywhere. Everyday. Everybody.

