

VARIANCE/HACCP Submission and Review Process

PRELIMINARY MEETING

A member of the Special Processes Team can call you to discuss your process and/or you can follow the Variance/HACCP Submission and Review Guide below. This guide will provide you with what is and is not allowable by regulation and the process. If you only require a variance and NOT a HACCP plan, the Variance Application will be provided. We can discuss via phone or an on-site visit, please call (972)-941-7143 and ask for a member of the Variance/HACCP Special Processes Team or email envhealth@plano.gov.

ELECTRONIC and/or HAND-DELIVERED SUBMISSION OF DOCUMENTS

- The variance application will be emailed to you for your completion and return along with your HACCP plan and SOP (if required) to envhealth@plano.gov, faxed 972-941-7142 or hand-delivered to 1520 K Avenue, Suite 210, Plano, Texas 75074.
- Sample HACCP plans can be found online or via a HACCP Consultant.
- A HACCP Consultant can prepare your HACCP plan if needed.
- A HACCP plan sample or template documents can be provided if needed.
- The following links can be useful in understanding HACCP:
<https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines>
- There will be \$200.00 variance fee that must be paid at the time of the initial application submittal in order to proceed.
- Variance Application and/or HACCP Plans submitted without the required items will not be accepted and returned for correction.

Specialized Processing

HACCP PLAN means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

OPERATIONAL PLAN/SOP means a written document that outlines a specific process.

VARIANCE means a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

“**SPECIAL PROCESSES**” are those retail food service processes that are more like food manufacturing processes rather than traditional retail or food service processes. Due to the high hazard nature of these production methods, the Regulations Governing the Sanitation of Food Establishments require a variance, operational plan, and/or HACCP plan to be submitted and approved.

§228.76. Specialized Processing Methods, Variance Requirement. §228.77. *Clostridium Botulinum* and *Listeria Monocytogenes* Controls. The approval of the plans and/or variance for special processes allows for retail production that would otherwise be prohibited.

Specialized processing method--A method of preparing certain foods that includes but is not limited to smoking food as a method of food preservation not as a method of flavor enhancement, curing food, using food additives or adding components to preserve and /or render a food so it is not a time / temperature controlled for safety food such as sushi rice, packaging food using a reduced oxygen method, operating a Molluscan shellfish life-support system display tank to store and display shellfish offered for human consumption, custom processing animals for personal use as food only such as indigenous deer processing, preparing food by a method determined by the regulatory authority as requiring a variance, or sprouting seeds or beans in a retail food establishment such as alfalfa or wheat grass.

Reduced oxygen packaging (ROP)--The reduction of the amount of oxygen in a package by removing oxygen, displacing oxygen and replacing it with another gas or combination of gases, or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level). It is a process that involves a food for which the hazards of *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form. ROP includes cook chill packaging, controlled atmosphere packaging, modified atmosphere packaging, Sous vide packaging, and vacuum packaging.

Sous vide packaging--A method of packaging food in which raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

Types of special processes and what plan and/or variance is required

PROCESS	HACCP PLAN	VARIANCE	OPERATIONAL PLAN/SOP	REGULATION REFERENCE
Smoking Food for Preservation	X	X		228.76 (1)
Using a Food Additive for Preservation or to Render a Food a Non-PHF/TCS	X	X		228.76 (3)
Curing Food	X	X		228.76 (2)
Cook-Chill ROP	X	X		228.76 (4), 228.77
Sous Vide ROP	X	X		228.76, 228.77
2-Barrier (vacuum packaging, modified atmosphere packaging, controlled atmosphere packaging) ROP	X			228.77
Cheese ROP	X	X		228.77 (5)
Fish ROP	X	X		228.77 (3)
Packaged Pasteurized Juice	X			
Packaged Unpasteurized Juice Onsite			X	228.74
Packaged Unpasteurized Juice Transported to Same Business Entity	X	X		
Molluscan Shellstock Tank	X	X		228.76 (5)
Custom Processing Animals for Personal Use	X	X		228.76 (6)
Sprouting Seeds or Beans	X	X		228.76 (8)
Bare Hand Contact with Ready to Eat Food		X	X	228.65
HACCP Plan Exemption for Federally (FDA,USDA) Approved HACCP Plan		X		
Preparing Food by an Alternate Method	X	X		228.76 (7)
Time as a Public Health Control			X	228.75 (i) (1)
Non-continuous cooking of raw animal food			X	228.71 (d)

INSTRUCTIONS for HACCP GUIDANCE

Developing a HACCP plan

1. There must be a thorough understanding of HACCP principles when developing a HACCP plan. Sample HACCP plans can be found online or via a HACCP Consultant.
2. The following links can be useful in understanding HACCP:
<https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines>

A HACCP Plan must contain the following:

1. A list of products that will be special processed
2. Equipment list and/or equipment spec sheets
3. A process flowchart must be included with CCP(s) identified
4. A Hazard Analysis must be completed with CCP(s) identified
5. (Optional) Process description/narrative
6. A HACCP chart or outline must be completed with CCP, Hazard Description, Critical Limit(s), CCP Monitoring Procedures (what are you monitoring, how, frequency, who will be monitoring), Corrective Action, Verification Activities with frequency (direct observation, thermometer calibration and records review), and Record Keeping (name of the logs)
7. Standard Operating procedures (prerequisite programs) must be included but not limited to:
 - Training program procedures
 - Cleaning and sanitizing procedures
 - Thermometer calibration procedures
 - Designated work area procedures
8. Monitoring Logs must be included such as:
 - pH monitoring log
 - Product temperature log
 - Thermometer calibration log
9. Make sure your HACCP plan is complete and customized to the processes in **YOUR** establishment or your HACCP plan will not be approved and you will not be able to conduct special processing.

REVIEW of VARIANCE APPLICATION and/or HACCP PLAN

- Once the variance application and/or HACCP plan have been received, the Health District will review the variance and/or HACCP plan in detail.
- Any errors found during the review will be provided via email, phone conversation or on-site visit.
 - The responsibility for assessing and correcting the errors falls upon the operator and/or consultant.
 - The corrected errors must be provided to the Special Process Team in order to proceed.
- If additional errors are identified, a corrections letter or email will be issued to the submitter.
- This process of review, corrections, and submission will continue until all documents are compliant.

FIELD EVALUATION LETTER or EMAIL for HACCP

- Once the variance/HACCP plan documentation is in compliance, the facility will be provided with a field evaluation letter or email stating the submitted documents are in compliance and final approval of the variance/HACCP plan is contingent upon a field evaluation. The requirements for the field evaluation are also stated in the letter.
 - The field evaluation is conducted at the facility to verify that the processes detailed in the variance/HACCP plan can be implemented as written.
- The operator must contact the Health District to schedule the field evaluation after all requirements detailed in the letter are in place.

FIELD EVALUATION for HACCP

- At the time of the field evaluation, if the processes can be successfully implemented, the variance/HACCP plan will be approved. It will be documented during the evaluation that the variance/HACCP plan can be implemented, and the process used.
 - If the facility does not demonstrate that the process can be properly implemented, the variance/HACCP plan will not be approved. An assessment form will be used to document the reason for the denial. A second field evaluation may be required.

APPROVAL LETTER

- After successful completion of the field evaluation, a formal letter will be issued to the facility detailing the approval of the variance/HACCP plan and the facility's responsibilities.
- ***Upon approval of this variance, the facility must remain in compliance with all terms and conditions of the variance. Failure to do so may result in withdrawal of the variance by the City of Plano and the facility will be required to bring all items into full compliance with the food code.***

HACCP AUDIT

- All retail food establishments performing activities that require a HACCP plan will be subjected to a HACCP audit to verify the proper implementation of your HACCP system. A member of the City of Plano Environmental Health Special Processes Team will conduct this audit.
- If significant changes have been made to the process or products under the HACCP plan, the auditor will require the facility to cease operation of HACCP foods.
- If the facility does not demonstrate that the process can be properly implemented, the Variance and HACCP system approval will be withdrawn.

For more information on Variance and/or HACCP plans, contact the Special Processes Team at (972) 941-7143 or email envhealth@plano.gov.