

HACCP



ROP/SOUS VIDE HACCP GUIDANCE

This guidance is for food service operators who want to use Reduced Oxygen Packaging (ROP) at their food service establishments and do not already have an approved Hazard Analysis Critical Control Point (HACCP) plan.

*For Retail Operators
Rev 2.0-5/23*

Carson City Health & Human Services
Environmental Health Division
900 E Long St.
Carson City, NV 89706
Tel: (775) 887-2190
Email: eh@carson.org



Reduced Oxygen Packaging Guidance for Food Service

Background Information

ROP is the process of placing food into a package, removing the oxygen from the package and sealing it, to keep food fresher for a longer time. ROP techniques include:

- **Vacuum Packaging.** Food is placed in a bag or packaging and the oxygen (air) is removed using a special vacuum packaging machine. The package is heat sealed or crimped closed.
- **Cook-Chill.** Cooked food is portioned into bags while hot. The bags are sealed or crimped closed, rapidly chilled and refrigerated. The cooking and cooling process removes oxygen from the package.
- **Sous Vide.** Raw or partially cooked food is sealed in a bag then cooked, usually at or near the desired final cooking temperature. The cooked food can be removed from the bag and served, hot held for service, or rapidly chilled and held under refrigeration until reheated for service.

Note: Canning processes also create a reduced oxygen environment. Canning of non-acidic “Low Acid” products is not permitted in retail establishments due to the high risk of botulism. Proper acidification can control the risk of botulism; therefore, acidic products (typically < 4.2) may be approved for canning at retail. Waiver & HACCP plan submission for “Acidification” rather than ROP may be required.

Certain dangerous bacteria such as Clostridium botulinum and Listeria monocytogenes grow well in reduced oxygen environments. When ROP is not done correctly, these bacteria can grow in the packaged food, making people seriously ill. Proper precautions must be taken for ROP to be carried out safely.

How to Obtain a Waiver to Use ROP

A food service establishment must have a plan approved by the health department before they can practice ROP. The plan must identify basic food safety practices such as time and temperature monitoring, proper cooling and organized food labeling.

Your establishment must be in good standing and demonstrate control of food safety risk factors in order to qualify for a waiver approval.

1. A waiver request application form must be completed and submitted to your local health inspector for review and approval.
2. If you do not already have a written HACCP plan fully developed to submit with the waiver, a supplemental information form completed in detail may be sufficient to function as a HACCP plan for some processes; however some processes may require full HACCP plans which must be reviewed and approved by a process authority.
University extension services may be useful for finding scientific support for your process.
i.e. (<http://www.douglasbaldwin.com/Baldwin-IJGFS-Preprint.pdf>), (<http://food-safety.guru/rop>)
3. Employees must be properly trained on your process. Training procedures should be included with your submission.
4. All critical control points in your process (CCP's) will require record keeping. Copies of the logs you will use should be included in your submission.

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Supplemental Information Form Options

There are two supplemental ROP information forms available depending on the type of foods being packaged and length of time they will be held. If you are unsure of which form to use, please contact your inspector.

Definitions: PHF or TCS = “Potentially Hazardous” or “Time-Temperature Control for Safety” are foods that require refrigeration to keep them safe)

Use the ROP HACCP Exemption Supplemental Information Form for:

- Vacuum packaging Non-PHF/TCS foods for any amount of time. (*Don't require refrigeration for safety*)
- Vacuum packaging, cook chill or sous vide methods for PHF/TCS food where food will be in packaging for **LESS than 48 hours** **AND** standard cook temps will be implemented per NAC 446.164.

Use the ROP HACCP Supplemental Information Form for:

- ROP foods that are held in the bag less than 48 hours, if the foods are cooked for extended periods to a final cooking temperature less than that required by NAC 446.164.
- ROP foods using vacuum packaging, cook chill or sous vide methods for TCS food where food will be in packaging for **LONGER than 48 hours**.

Special Requirements for ROP

Some pathogens can grow in ROP foods even when stored at normal refrigerated temperatures, so these foods require careful monitoring of storage times and temperatures. Follow these special precautions for ROP foods to ensure the safety of the food being packaged and served:

Labeling

Each individual package of food must be labeled with a permanent marker or other approved method with:

1. Product name.
2. Temperature to maintain food at (e.g. 41°F or 34°F).
3. Date item was sealed.
4. Date item must be used by or discarded.
5. If frozen for any length of time after packaging, mark the date packaged, date frozen, date thawed, and discard date.

Cooking

Cook Chill:

1. When using cook-chill, foods must reach the internal cooking temperature required per NAC 446.164. (i.e 165°F for Poultry, 155°F Ground Beef, etc.)
2. Food must be placed in the package and sealed immediately after cooking and before the food cools to less than 135°F.

Sous Vide:

1. When using sous vide, foods must be placed in the package and sealed prior to cooking.
2. Cook foods to an internal cooking temperature required per NAC 446.164 or other **approved method**. Cooking foods for extended periods to a final cooking temperature less than that required by NAC 446.164 requires **validated methods** from **credible** sources. Some previously approved methods are included in this document. Methods not included in this document may require review and approval from a process authority.
3. Foods may be immediately served after cooking, hot held, or cooled for storage.

Reduced Oxygen Packaging Guidance for Food Service

Cooling/Holding

1. **Raw** foods not cooked under ROP may be held at or below **41°F for up to 30 days** from the date the package is sealed. Raw foods may also be held frozen indefinitely. If a product was sealed and held at 41°F before it was frozen, subtract the number of days it was held prior to freezing from the 30-day limit, if you intend to store it.
2. All cooked ROP foods must be cooled from 135°F to 70°F within 2 hours and from 70°F to 41°F within an additional 4 hours.
 - a. Cook Chill
 - i. If the facility would like to hold cook chill foods at 34°F to extend the hold time, the foods must be cooled to 34°F within an additional 48 hours.
 - ii. Once properly cooled, cooked foods may be held at:
 1. Between 41°F and 34°F for 7 days from the date the package is sealed, or
 2. 34°F or below for up to 30 days from the date the package is sealed.
 - b. Sous Vide
 - i. Once properly cooled, cooked foods may be held at:
 1. Between 41°F and 34°F for 7 days from the date the package is sealed, or
 2. Frozen indefinitely.
3. Except where food will be held in ROP for less than 48 hours, **sous vide and cook-chill foods are to be held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature.** That unit must also be visually examined for proper operation twice daily. Electronic alarms that alert operators when a unit's internal temperature rises above a set parameter will satisfy this time and temperature requirement.

Off-Site Use

1. If sous vide and cook chill foods are transported off-site to a satellite location of the same business, verifiable electronic monitoring devices must be used to ensure that time and temperatures are monitored during transportation.
2. A food service establishment cannot sell ROP-packaged foods to consumers (e.g. vacuum packed foods to bring home) without a full HACCP plan reviewed and approved by a process authority.

Other

1. **Fish and seafood:** Fish that is vacuum packaged must be frozen throughout the packaging process (before, during and after packaging), and the bag must be opened prior to thawing. Label: "Keep Frozen; Cut Package Open Before Thawing"
2. **Cheeses:** Only unaltered, commercially manufactured hard cheese, pasteurized process cheese, or semi-soft cheese from a food processing plant with no ingredients added by the food service establishment may be used in ROP when ROP storage is greater than 48 hours.
3. **Record Keeping:** Records which are required as part of the ROP plan must be held on site for at least 6 months and be made available to the local health department upon request.

Reduced Oxygen Packaging Guidance for Food Service

Special Processes Requiring a Full HACCP Plan & Process Authority

The following are processes require a full HACCP plan, reviewed and approved by a process authority. The Carson City and Douglas County Public Health Regional Partnership reserves the right to require full HACCP and process authority review for any process when they deem is necessary. Contact info for several process authorities is available at:

<http://www.afdo.org/foodprocessing>.

Examples of processes requiring process authority approval include:

1. Cooking foods for extended periods to a final cooking temperature less than that required by NAC 446.164 other than the validated methods provided in this document.
2. Sous vide or cook chill of foods containing fish or seafood.
3. Vacuum packaging of “previously cooked and cooled” foods, except where foods are packaged for less than 48 hours. Modified or controlled atmosphere packaging.
4. Sous vide processes exceeding the standard 7-day rule.
5. Retail sale of ROP packaged foods.



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ROP HACCP Supplemental Information Form

For Vacuum Packaging, Cook Chill & Sous Vide

Any alterations, modifications or changes to an approved HACCP, must be resubmitted for review and approval of the Environmental Health Division.

General Information

Name of Owner & Title:	Phone:	
Establishment Name:	Email:	
Mailing Address:	City:	Zip Code:

HACCP TEAM Members

Name	Title / Role

1) List ROP equipment to be used (such as vacuum sealer, vacuum bags, circulator etc.)
 Or attach manufacturer's specification sheets. Record NA if not applicable.

Circulator	
Temperature Monitor	
Thermometers	
Vacuum Packager	
Sous Vide Bags	
Refrigerators	
Other	
Other	



ROP HACCP Supplemental Information Form

3) Vacuum packaging raw meat, poultry, or raw vegetables for storage at 41°F or less for up to 30 days and Food will be removed from ROP prior to cooking:

Basic HACCP is still required but a **custom flow chart is not needed**. **Refrigeration temperature is the only CCP requiring monitoring and record keeping**. Temperature must be checked twice daily. Refrigerated product stored past 30 days must be discarded. Product may be frozen for any length of time after packaging so long as labeling can indicate the date packaged, frozen, pulled and date to be discarded.

(You may skip step 4 if you are only vacuum packaging raw foods)

4) Sous vide or cook-chill process steps and critical controls.

(You may skip step 4 if you are only vacuum packaging raw foods)

Control Points in the ROP process are the steps in the flow of food from receiving to service.

Critical Control Points are steps that, when done correctly, can control the possibility of a food borne illness outbreak. An example is cooking chicken to an internal temperature of 165°F so Salmonella bacteria are destroyed OR rapidly cooling cooked products from 135°F to 70°F in 2 hours and from 70°F to 41°F in an additional 4 hours so Clostridium perfringens do not have an opportunity to grow.

Typically cooking, cooling, and cold storage following ROP are CCPs. Reheating may also a CCP if the food is being reheated for hot holding and not immediate service.

Critical Limits are the maximum or minimum value to which physical, biological or chemical parameters must be controlled at a CCP to minimize the risk of a foodborne illness outbreak. An example is cooking chicken to 165°F or cold holding product at 41°F or below for up to 7 days.

Corrective Actions are what is done to correct a step that's gone out of control. An example would be to continue to cook chicken temped at 145°F until it reaches 165°F OR discarding the sous vide products that have exceeded their labeled shelf life.



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ROP HACCP Supplemental Information Form

4) Sous vide or cook-chill process steps and critical controls - continued

Process Flow Instructions

- Examine the example process flows provided at the end of this document. Make one copy of the example process flow diagram for each product type you make. For example, if you make both sous vide and cook chill products you will need a flow diagram for each type.
- Use a highlighter or other pen to show the actual process flow you use for each product. Cross out any steps you don't use. Mark directional arrows as necessary to make the process clear. Add any other processing steps not already shown. You may list your preparation steps individually if desired.
- Once you have determined your flow steps, you should be able to draw out your process flow.

A) Describe your process for preparing each food item
Create a simple flow diagram from ingredient receiving to service
(Additional flows may be attached if needed for multiple processes or recipes)



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ROP HACCP Supplemental Information Form

B) What are the cooking times and temperatures for each item? (CCP)

Who takes the cooking temperature and how often?

What is the corrective action if the minimum cooking time and temp is not met?



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ROP HACCP Supplemental Information Form

4) Sous vide or cook-chill process steps and critical controls - continued

C) Describe how you will cool* your ROP products. (CCP)

**Standard parameters: 135°F to 70°F in 2 hours or less; 70°F to 41°F in an additional 4 hours or less.
 If desired, to 34°F in an additional 48 hours.*

Who takes the cooling temperatures and how often?

What is the corrective action if the minimum cooling time and temp is not met?

D) What temperature will you keep ROP products at once ready for storage? (CCP)

How long will you keep stored products? (i.e. Up to 7-days at ≤ 41°F or up to 30 days at ≤ 34°F)

How will you monitor the refrigeration unit? Sous vide and cook chill products must be held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily. *(Records required) Product specs may be attached.*



ROP HACCP Supplemental Information Form

4) Sous vide or cook-chill process steps and critical controls - continued

If transported off-site to a satellite location of the same business entity, verifiable electronic monitoring devices must be used to ensure that times and temperatures are monitored during transportation. How will you do this?

E) Describe how you will reheat the ROP Food

Will the food be hot held or immediately served?
If you are hot holding, the food must first be reheated to $\geq 165^{\circ}\text{F}$ (CCP)

5) Records: Attach copies of all logs to be used for record keeping. There must be a log for each CCP

Who verifies that records are being filled out correctly, how often, and where will your logs be kept?



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6) Labeling: Describe how food, once packaged, will be labeled so the package shall be prominently and conspicuously labeled using an indelible marker (or another approved method) on the principal display panel in bold type on a contrasting background, with:

- a) Product name.
- b) Temperature to maintain food at (41°F or 34°F).
- c) Date item was vacuum sealed.
- d) Date item must be discarded by if not served for on-premises consumption, or consumed if served or sold:
 - Up to 30 days stored at 41°F or less for raw meat, raw poultry, raw fruit or raw vegetables.
 - Up to 7 days stored at 41°F or less for cooked product.
 - Up to 30 days stored at 34°F or less for cooked product.
 - Frozen indefinitely.
- e) If frozen for any length of time after packaging: date packaged, date frozen, date pulled, and date to discard.

Label Description: (Attach label if available)



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ROP HACCP Supplemental Information Form

7) Describe or attach operational procedures for the following subjects

Identify a designated work for ROP and describe the methods that will be used to prevent cross contamination (A picture may be attached for reference if desired)

Describe how ROP processes and equipment will be limited to responsible trained personnel who understand the risk involved

Describe your procedures regarding operator hygiene and prohibiting bare hand contact with ready- to-eat foods



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ROP HACCP Supplemental Information Form

7) Describe or attach operational procedures for the following subjects - continued

Describe your cleaning and sanitizing procedures for food contact surfaces

Describe or attach your training program that ensures that staff involved in the ROP operation understand the concepts required for a safe operation

Describe or attach any additional information relevant to your process as needed



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ROP HACCP Supplemental Information Form

All ROP permit waiver applications must be submitted to your health inspector for review and approval prior to using ROP packaging in your establishment. Applications will be denied if the inspector believes the proposed HACCP plan does not take the proper precautions to keep the public from harm.

By signing and submitting this form to the permit issuing official you are requesting a waiver and establishing a plan to comply with the above requirements as conditions to using ROP for the foods listed on this form. Failure to implement ROP as described is subject to enforcement. Any additions or modifications to this plan must be reviewed and approved by the permit issuing official prior to being implemented.

I certify that I have knowledge of the facts herein set forth and that the same are true and correct to the best of my knowledge and belief.

Signature:

Date:

Any alterations, modifications or changes to an approved HACCP, must be resubmitted for review and approval of the Environmental Health Division.



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ROP HACCP Exemption Supplemental Information Form

- Non-TCS Foods (High Acid and/or Low Water activity)
- Temperature Controlled for Safety (TCS) Foods Packaged for less than 48 hours if cooked to standard temperature requirements per NAC 446.164

General Information			
Name of Owner & Title:		Phone:	
Establishment Name:		Email:	
Mailing Address:		City:	Zip Code:
Which ROP Process will be used? (Check one)			
<input type="checkbox"/> Vacuum packaging for storage	<input type="checkbox"/> Cook-Chill	<input type="checkbox"/> Sous Vide	
List of Foods That Will be Packaged Using Reduced Oxygen Packaging (ROP) Be specific; Additional information can be attached if needed.			
List ROP equipment to be used (such as vacuum sealer, vacuum bags, circulator etc.) Or attach manufacturer's specification sheets.			



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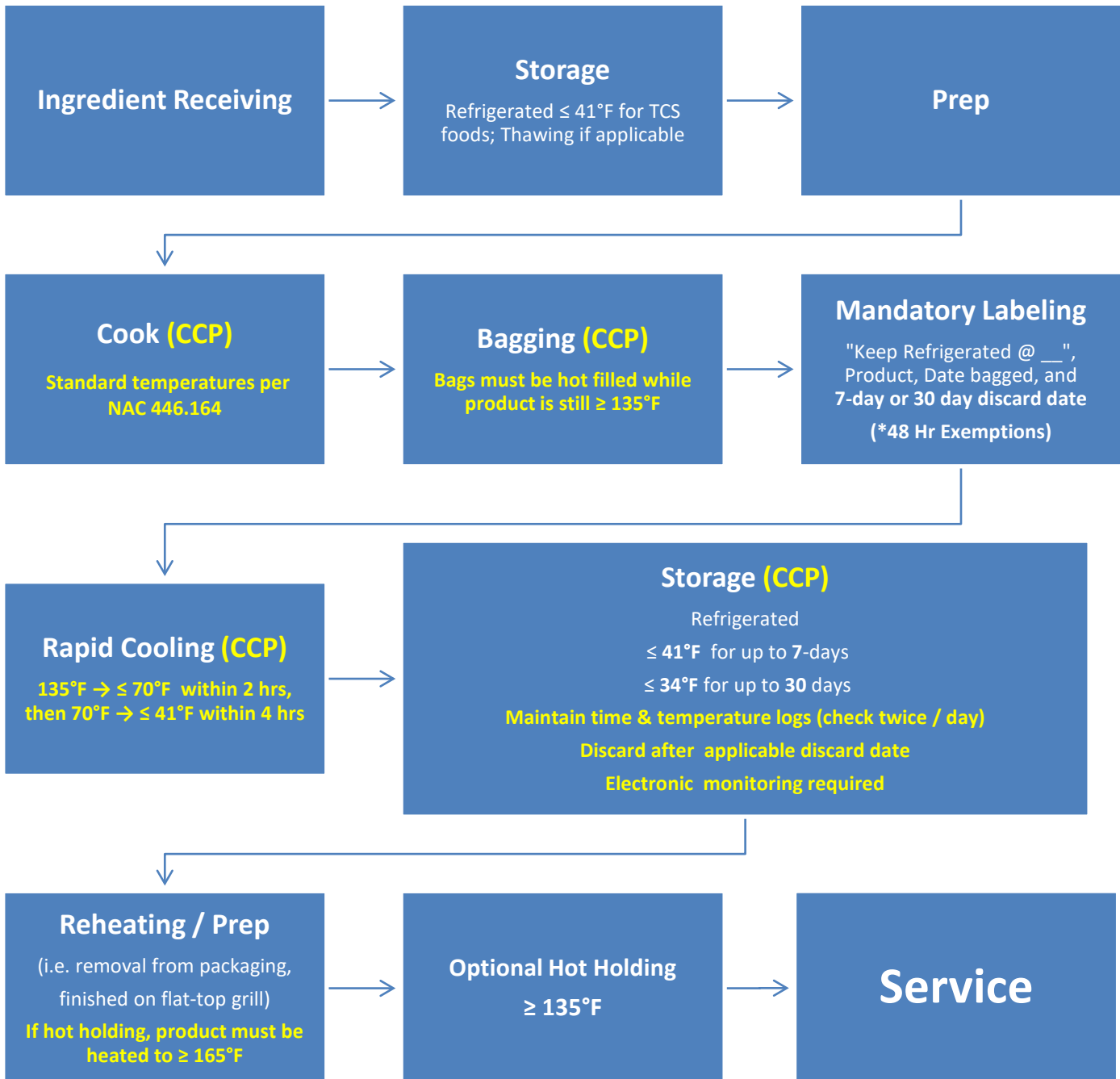


ROP HACCP Exemption Supplemental Information Form Continued:

Initial each statement to indicate understanding and agreement:	
	All ROP packaged foods must be labeled with product name, date and time packaged.
	Non-TCS foods may be held in ROP for an unrestricted length of time.
	TCS foods must be removed from ROP within 48 hours. During inspection, foods found in ROP for greater than 48 hours are subject to discard.
	TCS foods must be cooked to standard cook temps per NAC 446.164 in order to qualify for HACCP exemption.
	TCS foods placed into ROP while hot must be rapidly cooled from 135°F to 70°F in two hours or less, and to 41°F or less in an additional four hours.
	TCS foods in ROP must be held at 41°F or below at all times during refrigerated storage.
	Fish and/or Seafood may only be held in ROP if frozen before packaging, held frozen and removed from ROP before thawing. Label: "Keep Frozen; Cut Package Open Before Thawing" A scheduled process from a food processing authority is required if fish will be cooked sous vide.
<p>All ROP permit waiver applications must be submitted to your health inspector for review and approval prior to using ROP packaging in your establishment</p>	
<p>By signing and submitting this form to the permit issuing official you are requesting a waiver and establishing a plan to comply with the above requirements as conditions to using ROP for the foods listed on this form. Failure to implement ROP as described is subject to enforcement. Any additions or modifications to this plan must be reviewed and approved by the permit issuing official prior to being implemented.</p>	
<p><i>I certify that I have knowledge of the facts herein set forth and that the same are true and correct to the best of my knowledge and belief.</i></p>	
<p>Signature:</p>	<p>Date:</p>

Cook Chill HACCP Flow Example

Deadly **Botulism & Listeria** bacteria can thrive in vacuum sealed packages even under refrigeration. Careful monitoring and recording of **CCP times and temperatures** are critical to keeping the product safe.

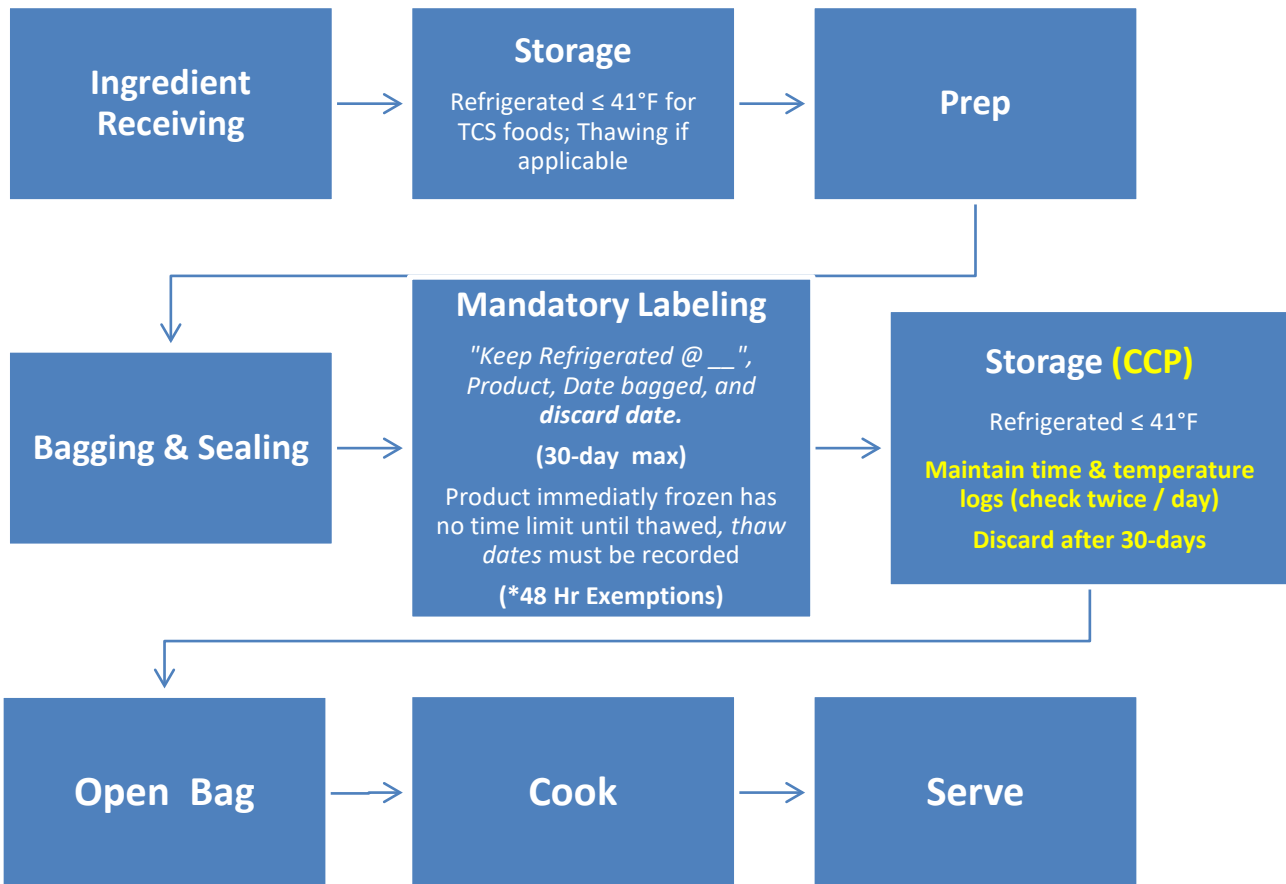


*HACCP exemption is available for ROP items that are in and out of the bag within **48 hours** when **standard cook temperatures per NAC 446.164** are also applied

****Fish and/or Seafood** may only be held in ROP if frozen before packaging, held frozen and removed from ROP before thawing due to a special type of Botulism that can grow rapidly in vacuum sealed low oxygen environments even at extremely low temperatures. A scheduled process from a food processing authority is required if fish will be cooked sous vide.

Vacuum Packaging for Raw Meat or Vegetables HACCP Flow Example

Deadly **Botulism & Listeria** bacteria can thrive in vacuum sealed packages even under refrigeration. Careful monitoring and recording of **CCP times and temperatures** are critical to keeping the product safe.

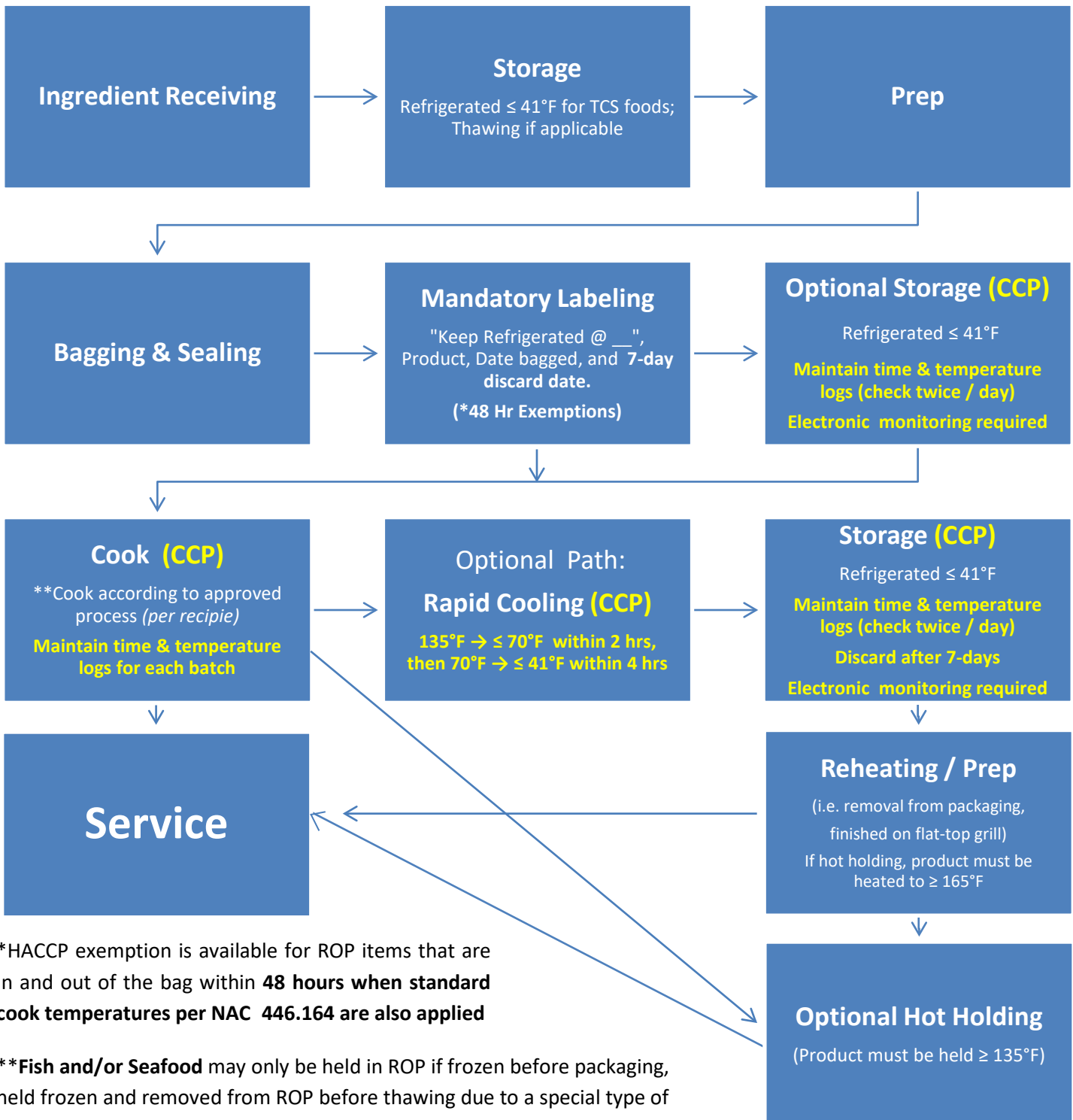


*HACCP exemption is available for ROP items that are in and out of the bag within **48 Hours**.
(i.e. ROP use only to infuse marinade)

****Fish and/or Seafood** may only be held in ROP if frozen before packaging, held frozen and removed from ROP before thawing due to a special type of Botulism that can grow rapidly in vacuum sealed low oxygen environments even at extremely low temperatures.

Sous Vide HACCP Flow Example

Deadly **Botulism & Listeria** bacteria can thrive in vacuum sealed packages even under refrigeration. Careful monitoring and recording of **CCP times and temperatures** are critical to keeping the product safe.



*HACCP exemption is available for ROP items that are in and out of the bag within **48 hours when standard cook temperatures per NAC 446.164 are also applied**

****Fish and/or Seafood** may only be held in ROP if frozen before packaging, held frozen and removed from ROP before thawing due to a special type of Botulism that can grow rapidly in vacuum sealed low oxygen environments even at extremely low temperatures. A scheduled process from a food processing authority is required if fish will be cooked sous vide.



Time and Temperature Table

Adapted from **Appendix A** of the FSIS Salmonella Compliance Guidelines for
 Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products
www.fsis.usda.gov

The following hold times start when the product reaches the internal temperature. Rise times may vary according to the thickness of the product. Temperature monitoring is essential to verifying both time and temperature parameters.

Temperature (°F)	Time for Beef 6.5 log Salmonella Lethality	Time for Chicken (up to 12% fat) 7-log Salmonella Lethality	Time for Turkey (up to 12% fat) 7-log Salmonella Lethality
130	112 min		
131	89 min		
132	71 min		
133	56 min		
134	45 min		
135	36 min		
136	28 min	81.4 min	70.8 min
137	23 min	65.5 min	58.5 min
138	18 min	52.9 min	48.5 min
139	15 min	43 min	40.4 min
140	12 min	35 min	33.7 min
141	9 min	28.7 min	28.2 min
142	8 min	23.5 min	23.7 min
143	6 min	19.3 min	19.8 min
144	5 min	15.9 min	16.6 min
145	4 min	13 min	13.8 min
146	169 sec	10.6 min	11.5 min
147	134 sec	8.6 min	9.4 min
148	107 sec	6.8 min	7.7 min
149	85 sec	5.4 min	6.2 min
150	67 sec	4.2 min	4.9 min
151	54 sec	3.1 min	3.8 min
152	43 sec	2.3 min	2.8 min
153	34 sec	1.6 min	2.1 min
154	27 sec	1.1 min	1.6 min
155	22 sec	54.4 sec	1.3 min
156	17 sec	43 sec	1 min
157	14 sec	34 sec	50.4 sec
158	0 sec	26.9 sec	40.9 sec
159	0 sec	21.3 sec	33.2 sec
160	0 sec	16.9 sec	26.96 sec
161	0 sec	13.3 sec	21.9 sec
162	0 sec	10.5 sec	17.7 sec
163	0 sec	< 10 sec	14.4 sec
164	0 sec	< 10 sec	11.7 sec
165	0 sec	< 10 sec	<10 sec



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REQUEST FOR FOOD ESTABLISHMENT WAIVER

As defined by NAC 446.039, a health hazard or nuisance may not result from the granting of the waiver in the opinion of health authority.

General Information					
Name of Person Requesting Waiver:		Title:		Establishment:	
Phone:		Cell:		Email:	
Street Address:			City:		Zip Code:
Mailing Address:			City, State:		Zip Code:
Type of waiver requested (Check one)					HACCP Food Safety Plan Required?
Smoking food as a method of food preservation rather than as a method of flavor enhancement (NAC 446.183(1)).					YES
Curing food (NAC 446.183(2)).					YES
Using food additives or adding components, including, without limitation, 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 (time/temperature control for food safety) (NAC 446.183(3)).					YES
Packaging food using a reduced oxygen packaging method, except as specified in this chapter, where a barrier to <i>Clostridium botulinum</i> in addition to refrigeration exists (NAC 446.183(4)).					YES
Operating a molluscan shellfish life-support system display tank used to store and display shellfish that are offered for human consumption (NAC 446.183(5)).					YES
Custom processing animals that are for personal use as food and not for sale or service in the food establishment (NAC 446.183(6)).					YES
Preparing food by another method that is determined by the health authority to require a waiver (NAC 446.183(7)), including but not limited to raw animal foods pursuant to NAC 446.164(4)(b).					YES
Sprouting seeds or beans (NAC 446.183(8)).					YES
Other – Rule modification or waiver request for items not involving specialized processes. <i>(Attach additional information)</i>					To Be Determined
Justification:					
* Attach written justification for why you believe the issuing of a waiver will not expose consumers to adverse environmental health conditions; will not create any health hazards; will not create a nuisance; and will protect the health and safety of the public and food service workers.					
Check the applicable types of supporting documents you have attached.					
Operational plans		Scientific study		Monitoring logs	
Labeling/disclaimers		HACCP plan		Written procedures	
				Validation study	
				Other	
<i>I certify that I have knowledge of the facts herein set forth and that the same are true and correct to the best of my knowledge and belief.</i>					
Signature:				Date:	

SECTION BELOW FOR OFFICIAL DEPARTMENT OF HEALTH USE ONLY

Action taken by the Public Health Authority:	
Granted	Denied
<i>Attach reasons for denial or the approval with waiver conditions and effective dates are attached.</i>	
REHS reviewer:	Date:
Manager, EHS:	Date: