

**FDA U.S. FOOD & DRUG
ADMINISTRATION**

Advanced Inspector Boot Camp
January 16, 2025

FDA Food Code Requirements for ROP

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FDA, Office of State Cooperative Programs

www.fda.gov/RetailFoodProtection

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FDA

Food Code Requires Variance & HACCP Plan for Specialized Processing Methods

- Smoking food for preservation (not flavor)
- Curing food
- Using food additives or adding components such as vinegar
 - As a method of food preservation
 - To render a food non-TCS




3-502.11, 8-201.13

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FDA

Food Code Requires Variance & HACCP Plan for Specialized Processing Methods

- Operating a molluscan shellfish display tank.
- Custom processing animals for personal use.
- Sprouting seeds or beans.
- Any method determined by the RA to require a variance.
- Packaging TCS food using a ROP method **except where *C. bot.* and *L. mono.* are controlled under § 3-502.12.**



3-502.11, 8-201.13

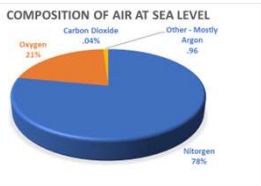
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FDA

ROP Food Code Definition

The reduction of the amount of oxygen in a package by:

- Removing oxygen
- Displacing and replacing oxygen with other gas or gasses, or
- Otherwise controlling the oxygen content to < normal at sea level (21%) and
- Involves food for which the hazards *C. bot.* or *L. mono.* Require control in the final packaged form.




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FDA

Vacuum Packaging

- Vacuum packaging
 - Air is removed from a package
 - The package is hermetically sealed so that a vacuum remains inside the package.



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FDA

Modified Atmosphere (MAP) & Controlled Atmosphere Packaging (CAP)

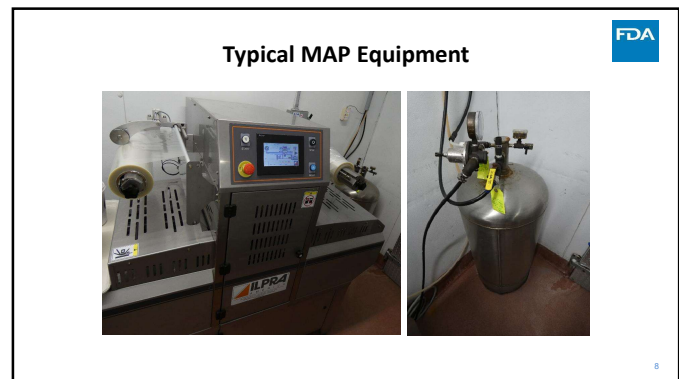
- Modified atmosphere packaging (MAP)
 - Atmosphere of a package of food is modified so that its composition is different from air.
 - Atmosphere may change over time
 - permeability of the packaging
 - respiration of the food.
 - MAP includes
 - Reduction in the % of oxygen
 - Total replacement of oxygen, or
 - Increase in the proportion of other gases (carbon dioxide, nitrogen)
- Controlled atmosphere packaging (CAP)
 - Modified so that until the package is opened, its composition is different from air, and continuously controlled
 - Using oxygen scavengers or
 - a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

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Cook Chill Packaging

- **Cook-chill packaging**, in which cooked food is **hot filled** into impermeable bags that are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

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Sous Vide Packaging:

- 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.

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Why the Fuss?

- *Listeria monocytogenes*
 - Facultative anaerobe
 - Growth at refrigerated temperatures
 - Ubiquitous: Air, soil, water, food products, animals
 - Serious illness in elderly, young, immunocompromised, and pregnant women
- *Clostridium botulinum*
 - Anaerobe
 - Some types grow at refrigerator temps – Types E and non-proteolytic B&F (3BF), found in marine/aquatic environments.
 - Vegetative cells relatively easy to kill with heat, but organism produces spores which are very heat resistant and survive normal cooking temperatures
 - Produces a neurotoxin, one of the deadliest naturally occurring substances known.

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**ROP without a variance:
3-502.12 HACCP Plan Required**

Foods with 2 barriers

- AW of 0.91 or less
- PH of 4.6 or less
- MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA
- FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables

Cheeses: commercially manufactured in a food processing plant with no ingredients added

Fish: must be frozen before, during, and after ROP. Otherwise, variance is always needed.

Cook-chill & sous vide

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Cook-Chill & Sous Vide Without a Variance



- The following excludes FISH
- Provide a HACCP plan to RA prior to processing Ensures food is:
 - Prepared and consumed on the premises (or off premises within same business entity).
 - No sales to other businesses or directly to consumers.



3-502.12 (D)

<http://www.foodprotect.org/guides-documents/single-hazard-special-process-haccp-template-guidance-document-and-sample-templates/>

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Cook-Chill & Sous Vide Without a Variance



- Cooked in accordance with 3-401.11 (A), (B), and (C).



3-502.12 (D)

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Cook-Chill & Sous Vide Without a Variance



- Protected from contamination before and after cooking
- Placed in a package with an oxygen barrier and sealed
 - before cooking, or
 - placed in a PACKAGE and sealed immediately after cooking and before reaching a 135°F



3-502.12 (D)

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Cook-Chill & Sous Vide Without a Variance



- Cooled to 5°C (41°F) in the sealed package per the Code and:
 - Held at 41°F ≤ 7 days and consumed or discarded; or
 - Cooled to 34°F within 48 hrs. of reaching 41°F = 30-day shelf life;
 - Cooled to 34°F within 48 hours of reaching 41°F; removed from 34°F; and maintained at 41°F ≤ 7 days (can't exceed 30 days);
 - Held frozen with no shelf-life restriction while frozen.



3-502.12 (D)

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Cook-Chill & Sous Vide Without a Variance



- 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.
- If transported offsite: verifiable electronic monitoring



3-502.12 (D)

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Other Requirements



- Labeled with product name & date packaged.
- Maintain cooling and cold holding records for 6 mos. for regulatory review.
- Operational procedures:
 - Prohibit BHC with RTE
 - Designated work area
 - Cleaning/sanitizing procedures
- Training program
 - Concepts for safe operation
 - Equipment use & operational procedures



3-502.12 (D)

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ROP Methods Without a Variance or HACCP Plan



- A HACCP Plan is not required for ROP packaging methods to package TCS food that is always:
 - (1) Labeled with the production **time and date**,
 - (2) Held at 5°C (41°F) or less during refrigerated storage, and
 - (3) Removed from its package in the food establishment **within 48 hours** after packaging.
- Not FISH

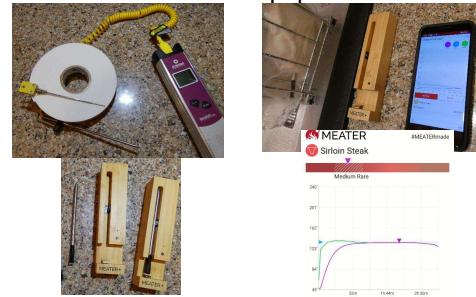


3-502.11 (F)

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Possible Additional Sous Vide Equipment



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Question 1



With this type of ROP, cooked food is hot filled into impermeable bags that are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated.

- A) Vacuum Packaging
- B) Cook chill
- C) Sous vide
- D) Controlled atmosphere packaging (CAP)

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Question 2



With this type of ROP method, air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package.

- A) Vacuum Packaging
- B) Cook chill
- C) Sous vide
- D) Modified atmosphere packaging (MAP)

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Question 3



In this type of ROP packaging, raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated.

- A) Vacuum Packaging
- B) Cook chill
- C) Sous vide
- D) Modified atmosphere packaging (MAP)

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Question 4



Retail establishments may use ROP methods on TCS foods without a variance if the provisions of 3-502.12 (B) are followed exactly as written and it is a food with a high level of competing organisms such as raw meat, raw poultry, raw vegetables, or fresh raw fish.

- True
- False

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Question 5

For preparation without a variance, Cook-chill and sous vide products must be cooked according to time/temperatures as specified under 3-401.11 (A), (B), and (C) unless a consumer advisory is provided as detailed in 3-603.11.

- True
- False

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HACCP Plan Validation, Review and Approval

Carrie Pohjola, Division of Food and Recreation Safety

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HACCP PLAN BASICS

- Food Flow
- Hazard Analysis
- Critical Control Point
- Critical Limits
- Monitoring Procedures
- SOPs/Prerequisite Programs

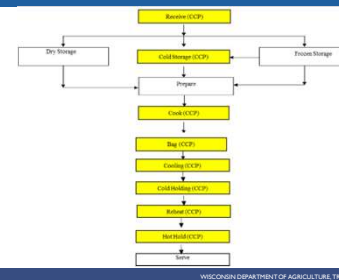


This is the easy part!



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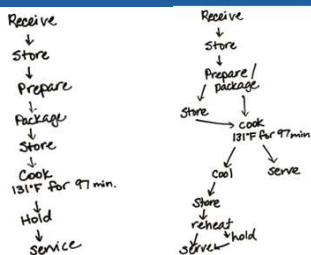
WHAT WOULD YOU DO?



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FOOD FLOW EXAMPLES: SOUS VIDE OF PORK



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FOOD FLOW EXAMPLES

Receive → Store → Prepare → Package → Store → Cook → Hold → Serve

1. Receive
 2. Store
 3. Prepare
 4. Package
 5. Store
 6. Cook
 7. Hold
 8. Serve
- First, we receive the produce from our supplier.
 - Then, we store the product in our walk-in cooler.
 - Then, we prepare the product.
 - Then, we package the product in ROP.
 - We store the product in ROP packaging.
 - Then, we cook the product to 131°F for 91 minutes.
 - We hold the product in a steam table above 135°F.
 - Then, we serve it.



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POLL QUESTION

Canned Spaghetti Sauce
Ground Beef
Onions, Garlic
Parmesan Cheese
Herbs (Oregano, Basil)
Sugar
Red Wine

1. Add ground beef to steam kettle, cook until meat reaches 155°F. Drain.
2. Add onions and garlic. Sauté.
3. Add spaghetti sauce, salt, herbs, sugars, red wine, cheese. Stir.
4. Heat to 190°F; then simmer while stirring.
5. Portion into bags.
6. Seal bags.
7. Place in ice bath to cool.
8. Remove and place in cooler.
9. Refrigerate and store.
10. Reheat and serve.

Which of the following is a primary hazard of concern for this process?

- A. Salmonella
B. Bacillus Cereus
C. Clostridium Botulinum



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POLL QUESTION

Canned Spaghetti Sauce
Ground Beef
Onions, Garlic
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5. Portion into bags.
6. Seal bags.
7. Place in ice bath to cool.
8. Remove and place in cooler.
9. Refrigerate and store.
10. Reheat and serve.

Which steps are the CCPs?

- A. 1 and 4
B. 6 and 9
C. 4 and 7



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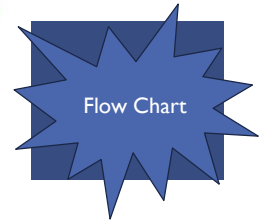
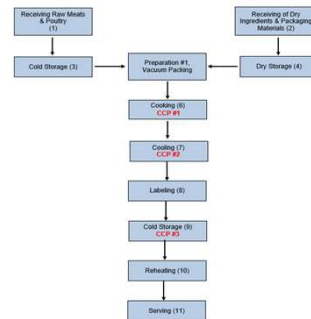
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FOOD FLOW EXAMPLES: SOUS VIDE



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HAZARD ANALYSIS

Process Step	Control Measure (CCP)	Residual Hazard	Justification of Control Measure	Control Measure	CCP
Receiving Raw Meats & Poultry (1)	(1) Receiving (1) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Meat and poultry will be cooked to minimum internal temperature and will be held at 155°F for 15 seconds.	Thermometer Log	Yes
Receiving Dry Ingredients & Packaging Materials (2)	(2) Receiving (2) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Dry ingredients will be stored in a cool, dry place and will be used within 6 months.	Thermometer Log	Yes
Cold Storage (3)	(3) Cold Storage (3) Critical Limits: 0°F to 1°F	Salmonella, E. coli, etc.	Meat and poultry will be stored at 0°F to 1°F for 14 days.	Thermometer Log	Yes
Preparation #1, Vacuum Packaging (4)	(4) Preparation (4) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Meat and poultry will be cooked to minimum internal temperature and will be held at 155°F for 15 seconds.	Thermometer Log	Yes
Cooking (6)	(6) Cooking (6) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Meat and poultry will be cooked to minimum internal temperature and will be held at 155°F for 15 seconds.	Thermometer Log	Yes
Cooling (7)	(7) Cooling (7) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Meat and poultry will be cooled to 155°F for 15 seconds.	Thermometer Log	Yes
Labeling (8)	(8) Labeling (8) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Meat and poultry will be labeled with the name of the product and the date of production.	Thermometer Log	Yes
Cold Storage (9)	(9) Cold Storage (9) Critical Limits: 0°F to 1°F	Salmonella, E. coli, etc.	Meat and poultry will be stored at 0°F to 1°F for 14 days.	Thermometer Log	Yes
Reheating (10)	(10) Reheating (10) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Meat and poultry will be reheated to 155°F for 15 seconds.	Thermometer Log	Yes
Serving (11)	(11) Serving (11) Critical Limits: 155°F for 15 seconds	Salmonella, E. coli, etc.	Meat and poultry will be served at 155°F for 15 seconds.	Thermometer Log	Yes



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HACCP FORM

(1) Critical Control Point	(2) Hazard Description	(3) Critical Limits	(4) What	(5) When	(6) Frequency	(7) Who	(8) Corrective Action	(9) Verification Activities	(10) Record Keeping Procedures
Cooking (CCP 1)	Pathogens	Temperature: 155°F for 15 seconds	Product temperature	Use of thermometer	One food product per batch	Designated food worker	Continue cooking and adjust controller range (Thermometer) designated long by product	Cooking Log reviewed daily to date	Thermometer Validation Log reviewed by chef's annually
Cooling (CCP 2)	Pathogens	Temperature: 155°F for 15 seconds	Product temperature	Use of thermometer	Every hour	Designated food worker	Reheat to cooking temp and return to 155°F for 15 seconds	Cooling Log reviewed daily to date	Thermometer Validation Log reviewed by chef's annually
Cold Storage (CCP 3)	Pathogens	Temperature: 0°F to 1°F	Cooler and product temperature	Use of thermometer	Continuous electronic monitoring, as well as 2x daily (visual checks)	Designated food worker	Immediately discard product if range is outside 4°F (Thermometer) and immediately return to 0°F to 1°F	Refrigeration/Freezer Log reviewed daily to date	Refrigeration/Freezer Log reviewed by chef's annually

HACCP Plan



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POLL QUESTION

Could you approve a HACCP plan with this food flow?

☐ Yes
☒ No

Correct Answer – No, store/label CCP is missing, and you cannot approve a plan if there are missing CCPs.

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WHAT IS VALIDATION?

Validation – will the process control the hazards as designed?

- Completed by operator
 - Sometimes done informally, operator has validated once they have turned it in
- Completed by regulator
 - Regulatory authority agrees or disagrees with operators' validation

Validation	Before
Monitoring	During
Verification	After



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REDUCE OXYGEN PACKAGING VALIDATION CONSIDERATIONS

Compliance with Food Code Section 3-502.12

- Time/temperature requirements
- Final cook temperatures
- Cook/chill or sous vide not sold in package to consumer
- Labeling for raw meat ROP

Is Additional Science Being Used?

- Equivalent Lethality
- Alternate Monitoring Procedures

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MONITORING AND EQUIVALENT LETHALITY

Using FSIS Appendix A, will not reach FDA Food Code Final Cook Temps

Cannot meet 3-502.12, will need a variance

Commonly used alternate validation

Will need to monitor both time and temperature

Not instantaneous cooking temperature like food code cooking temperature

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USDA-FSIS APPENDIX A

<https://www.fsis.usda.gov/news-events/events-meetings/revised-appendix-b-guidelines>


Table 3. Time-Temperature Combinations for Meat Products to Achieve Lethality

Cooking Temperature (°F)	Minimum Internal Temperature (°F)	Time (min)	Equivalent Lethality (log reduction)
125	125	100	1.0
130	130	60	1.0
135	135	40	1.0
140	140	30	1.0
145	145	25	1.0
150	150	20	1.0
155	155	15	1.0
160	160	12	1.0
165	165	10	1.0
170	170	8	1.0
175	175	7	1.0
180	180	6	1.0
185	185	5	1.0
190	190	4	1.0
195	195	3	1.0
200	200	3	1.0
205	205	2	1.0
210	210	2	1.0
215	215	2	1.0
220	220	1	1.0
225	225	1	1.0
230	230	1	1.0
235	235	1	1.0
240	240	1	1.0
245	245	1	1.0
250	250	1	1.0
255	255	1	1.0
260	260	1	1.0
265	265	1	1.0
270	270	1	1.0
275	275	1	1.0
280	280	1	1.0
285	285	1	1.0
290	290	1	1.0
295	295	1	1.0
300	300	1	1.0
305	305	1	1.0
310	310	1	1.0
315	315	1	1.0
320	320	1	1.0
325	325	1	1.0
330	330	1	1.0
335	335	1	1.0
340	340	1	1.0
345	345	1	1.0
350	350	1	1.0
355	355	1	1.0
360	360	1	1.0
365	365	1	1.0
370	370	1	1.0
375	375	1	1.0
380	380	1	1.0
385	385	1	1.0
390	390	1	1.0
395	395	1	1.0
400	400	1	1.0
405	405	1	1.0
410	410	1	1.0
415	415	1	1.0
420	420	1	1.0
425	425	1	1.0
430	430	1	1.0
435	435	1	1.0
440	440	1	1.0
445	445	1	1.0
450	450	1	1.0
455	455	1	1.0
460	460	1	1.0
465	465	1	1.0
470	470	1	1.0
475	475	1	1.0
480	480	1	1.0
485	485	1	1.0
490	490	1	1.0
495	495	1	1.0
500	500	1	1.0
505	505	1	1.0
510	510	1	1.0
515	515	1	1.0
520	520	1	1.0
525	525	1	1.0
530	530	1	1.0
535	535	1	1.0
540	540	1	1.0
545	545	1	1.0
550	550	1	1.0
555	555	1	1.0
560	560	1	1.0
565	565	1	1.0
570	570	1	1.0
575	575	1	1.0
580	580	1	1.0
585	585	1	1.0
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610	610	1	1.0
615	615	1	1.0
620	620	1	1.0
625	625	1	1.0
630	630	1	1.0
635	635	1	1.0
640	640	1	1.0
645	645	1	1.0
650	650	1	1.0
655	655	1	1.0
660	660	1	1.0
665	665	1	1.0
670	670	1	1.0
675	675	1	1.0
680	680	1	1.0
685	685	1	1.0
690	690	1	1.0
695	695	1	1.0
700	700	1	1.0
705	705	1	1.0
710	710	1	1.0
715	715	1	1.0
720	720	1	1.0
725	725	1	1.0
730	730	1	1.0
735	735	1	1.0
740	740	1	1.0
745	745	1	1.0
750	750	1	1.0
755	755	1	1.0
760	760	1	1.0
765	765	1	1.0
770	770	1	1.0
775	775	1	1.0
780	780	1	1.0
785	785	1	1.0
790	790	1	1.0
795	795	1	1.0
800	800	1	1.0
805	805	1	1.0
810	810	1	1.0
815	815	1	1.0
820	820	1	1.0
825	825	1	1.0
830	830	1	1.0
835	835	1	1.0
840	840	1	1.0
845	845	1	1.0
850	850	1	1.0
855	855	1	1.0
860	860	1	1.0
865	865	1	1.0
870	870	1	1.0
875	875	1	1.0
880	880	1	1.0
885	885	1	1.0
890	890	1	1.0
895	895	1	1.0
900	900	1	1.0
905	905	1	1.0
910	910	1	1.0
915	915	1	1.0
920	920	1	1.0
925	925	1	1.0
930	930	1	1.0
935	935	1	1.0
940	940	1	1.0
945	945	1	1.0
950	950	1	1.0
955	955	1	1.0
960	960	1	1.0
965	965	1	1.0
970	970	1	1.0
975	975	1	1.0
980	980	1	1.0
985	985	1	1.0
990	990	1	1.0
995	995	1	1.0
1000	1000	1	1.0

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HACCP Monitoring Procedures



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VALIDATED MONITORING PROCEDURES



- Other monitoring methods exist
- Internal temperature is "easy button"
- Operators can use other validated methods

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VALIDATED MONITORING PROCEDURES

Table 2
Time sufficient to pasteurize meat, fish, or poultry in water baths from 15 °C (59 °F) to 60 °C (140 °F). This table is based on the internationally accepted and generally conservative 2 min. at 70 °C (158 °F) with $\alpha = 7.5 \text{ } ^\circ\text{C}^{-1}$ (13.3 °F for a million to one reduction in *Listeria monocytogenes* and applies to all foods (FDA, 2011). For low conservative pasteurization times, see Baldwin (2009) and Fig. 5. This calculation uses a thermal diffusivity of $1.1 \times 10^{-7} \text{ m}^2/\text{s}$, a surface heat transfer coefficient of $95 \text{ W/m}^2 \cdot \text{K}$, and $\beta = 0$ up to 30 mm and $\beta = 0.28$ above 30 mm in °F.

Thickness (mm)	55 °C / 131 °F	56 °C / 132.8 °F	57 °C / 134.6 °F	58 °C / 136.4 °F	59 °C / 138.2 °F	60 °C / 140 °F
5	3.33	2.41	2.00	1.30	1.08	0.51
10	3.35	2.43	2.04	1.36	1.15	1.00
15	3.46	2.55	2.16	1.48	1.28	1.13
20	4.05	3.11	2.32	2.04	1.44	1.28
25	4.17	3.25	2.46	2.18	1.57	1.41
30	4.29	3.38	2.60	2.32	1.71	1.55
35	4.45	3.53	2.75	2.46	1.85	1.69
40	4.59	3.67	2.89	2.60	1.99	1.83
45	5.21	4.29	3.50	3.22	2.60	2.42
50	5.45	4.53	4.14	3.44	3.21	3.03
55	6.10	5.18	4.79	4.08	3.85	3.58
60	6.38	5.45	5.06	4.35	4.10	3.80
65	7.07	6.15	5.74	5.02	4.76	4.15
70	7.40	6.48	6.03	5.30	5.04	4.42


Douglas E. Baldwin, Sous vide cooking: A Review, International Journal of Gastronomy and Food Science, Volume 1, Issue 1, 2012, Pages 15-30.

- Measuring thickness instead of internal temperature
- "Come up time" included

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VALIDATED MONITORING PROCEDURES



Different equipment used


Additional SOPs

Monitoring procedure must match validated process

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MONITORING AND EQUIVALENT LETHALITY



When monitoring sous vide cooking temperatures, recording the temperatures (without further scientific evidence) of the water bath is sufficient for monitoring procedures?

- True
- False**

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FILE REVIEW AND HACCP APPROVAL

- Previous inspections are part of approving HACCP Plan
- What documentation is available?
- Active Managerial Control
- Cooling/Space considerations

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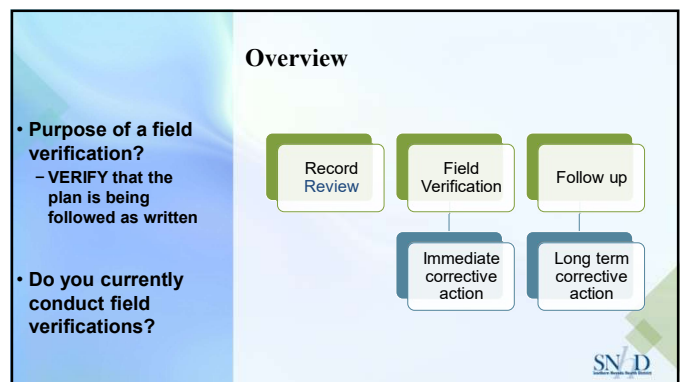
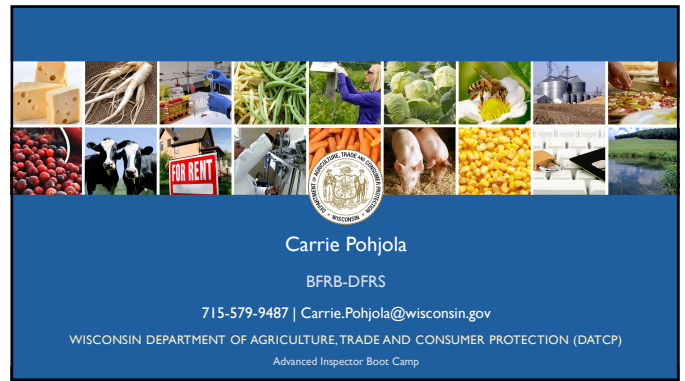
REMEMBER...



- Retail HACCP Builds on Food Code
- Look for unique hazards or processes outside the code
- Operators can have extra items in plan
- Cannot leave out critical items

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File Review

- Products
- Process Flow
- CCP Summary
- Logs
- Previous compliance issues

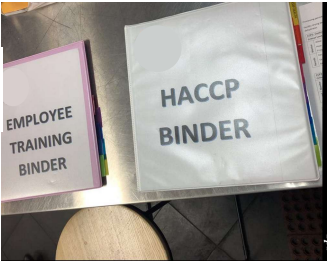
Proteins - Sous Vide Worksheet

DATE	TIME	Food Item/Recipe	Order Date	Order
10/26/21	12:00	Protein: Chicken Breast Recipe: Chicken Breast, Sous Vide, 120°F, 2 hours Instructions: Chicken Breast, Sous Vide, 120°F, 2 hours Notes: Chicken Breast, Sous Vide, 120°F, 2 hours		
10/26/21	12:00	Protein: Chicken Breast Recipe: Chicken Breast, Sous Vide, 120°F, 2 hours Instructions: Chicken Breast, Sous Vide, 120°F, 2 hours Notes: Chicken Breast, Sous Vide, 120°F, 2 hours		





Two binders are shown on a table. The binder on the left is labeled "EMPLOYEE TRAINING BINDER" and the binder on the right is labeled "HACCP BINDER".



Verify Knowledge/ Training

- When is the best time to verify knowledge/training?
- Observe processing
 - Following described procedures
- Ask questions throughout field verification/inspection
 - Open ended questions
 - Critical limits
 - Monitoring procedures
- Training Records

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Ingredients

BEEF

- Black Angus Choice Fillet 8 oz.
- Black Angus Choice Fillet 9 oz.
- Black Angus Choice Fillet 12 oz.
- Black Angus Choice Fillet 20 oz.
- Choice New York 12 oz.
- Prime Block Cut Sirloin 6 oz.
- Prime Rib-eye 20-22 oz.
- Tenderloin Chuck Roll LB
- Prime Porterhouse 40 oz.
- Steak Ends LB
- Triangles LB
- Tenderloin Tips LB

PORK

- Chop 3.5 oz.

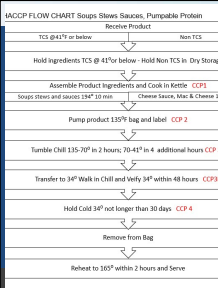

CHICKEN

- Breast Sliced LB



Verify Product Description

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Verify Process Flow


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Verify Critical Limits are met

- Specified in the plan



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Verify Monitoring Procedures


- What
- How
- Frequency

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Verify Immediate Corrective Action

During a verification of a cook chill facility, you observe product being packaged at a temperature below the required temperature. What corrective action should be taken?

- Remove it from ROP and do not package that batch
- Reheat the product and restart the packaging process
- Discard the batch
- Take the action detailed in the HACCP plan



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Verify Immediate Corrective Action

- Verify that the written Corrective Actions are followed for out of compliance issues




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Long Term Corrective Action

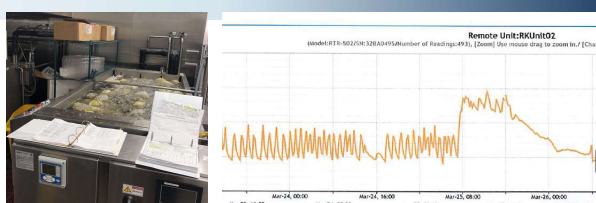
When should the HACCP approval be revoked?

Level of Non-compliance	Corrective Action
Missed Critical Limit	Immediate correction, including discarding of food if justified, follow up within 10 days to ensure continuing compliance
Missed monitoring of critical limit	Immediate correction, have employees begin monitoring during visit, follow-up within 10 days to ensure continuing compliance
Other areas of non-compliance	Follow-up within 30 days to make sure either the plan has been changed or procedure has changed




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Verify Record Keeping and Person in Charge Verification



- Documentation
 - HACCP Plan and approval
 - Records
 - CCPs
 - Corrective actions
 - Prerequisites (e.g., calibration records)



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Verify Record Keeping and Person in Charge Verification

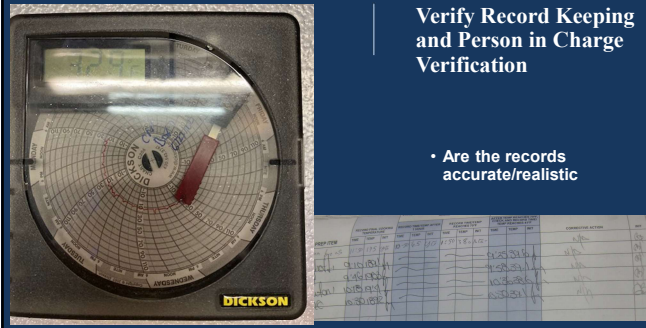
- Records complete?
 - Monitoring
 - Corrective actions
 - Verification
 - Min of 3 batches/products
- Record maintained per plan?



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Verify Record Keeping and Person in Charge Verification

- Are the records accurate/realistic



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Verify Prerequisites

- Proper calibration of equipment
 - Method
 - Frequency
 - Documentation
- Other Prerequisites



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