



SEPTEMBER 2020

Commercial Processing Example: *Shucked Oysters*

Example: This is a Special Training Model for illustrative purposes only. The SHA models for molluscan shellfish are based on requirements in the National Shellfish Sanitation Program Model Ordinance (NSSP) and the FDA’s *Fish and Fishery Products Hazards and Control Guidance* (4th edition, 2020) and additional information available on FDA website. This model was produced by the National Seafood HACCP Alliance (SHA) strictly as an example for training and may not apply to all situations.

SPECIAL NOTE: This HACCP model cites numerous references sourced from the FDA website under the National Shellfish Sanitation Program’s (NSSP) Model Ordinance (revised 2017) that are designated as ‘MO – with citations.’

Narrative

Company	ABC Oyster Company, Anywhere, USA
Market Name	Oysters (<i>Crassostrea virginica</i>)
Source of Fishery Product	Purchased from other dealers and transported in a refrigerated truck
Describe the Food	Shucked oyster meat
Method of Receiving, Storage and Distribution	Oysters are received from other dealers in tagged containers (such as bags, boxes, or bulk containers), during non-Vibrio control months, live in the shell, and chilled to 45°F/7.2°C or less. Shellstock is placed into cooler storage until ready for processing. Shucked oyster meats are stored in containers surrounded by ice and under refrigerated storage at 45°F/7.2°C or less, until distributed.
Finished Packaging Type	Raw shucked oysters in plastic cups (pint/16 oz. and quarts/32 oz.)
Intended Use and Consumer	Shucked oysters are a raw ready-to-eat product that could be eaten raw or cooked by the general public.

Description of Process

Receive oyster shellstock - Oyster shellstock is received live from other dealers with dealer tags affixed to each container of shellstock (such as bags, boxes, or bulk containers) and chilled to 45°F (7.2°C) or less, and transported in a refrigerated truck. Dealer tags are checked for dealer name and address, certification number, original shellstock shipper number, harvest date and location, type and quantity of shellstock, consistent with requirements outlined in MO Chapter X. 05B.

Shellstock refrigerated storage – The shellstock are immediately placed into refrigerated storage at 45°F/7.2°C until needed for processing.

Wash – On an as needed basis, shellstock is removed from storage and placed on conveyers where it is washed.

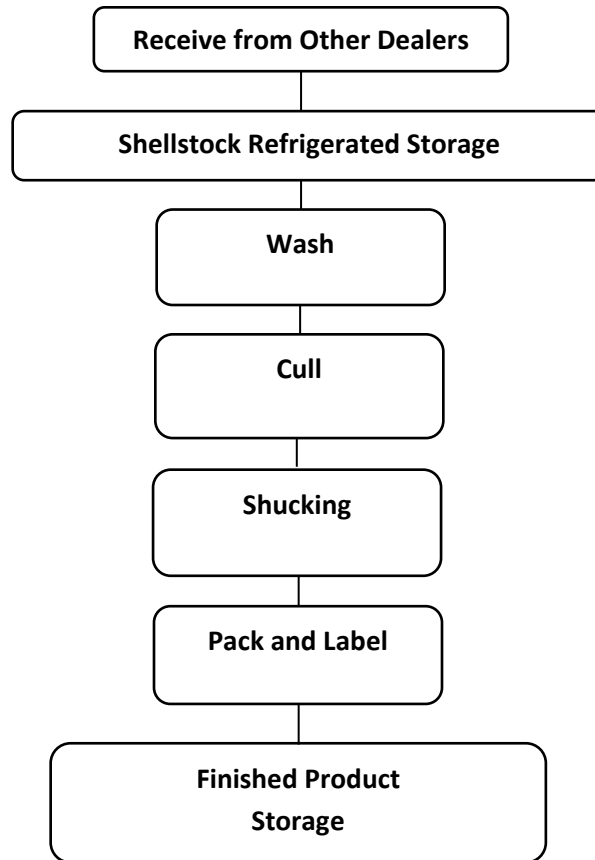
Cull – Washed oysters are culled, graded and distributed to the shucking stations.

Shucking – Shellstock is shucked by manually separating the meat from the shell with a shucking knife. The oyster meat is placed into stainless steel buckets filled with ice slush. Once the bucket is full (approximately 20 min), it is delivered to the packing room. The cumulative time for the wash, cull and shuck steps are less than 1 hour.

Pack and label - Shucked oyster meats are rinsed, graded and packed into the final pre-labeled plastic cups. Containers are packed in waxed boxes, and covered with ice. This step takes less than 30 minutes.

Finished product storage – Boxes with containers of shucked oysters buried in ice under refrigeration 45°F/7.2°C or less until they are distributed. [MO Chapter XI .01 E]

Shucked Oyster Meats Process Flow Chart



Commercial Processing Example: *Shucked Oysters*

Example: For Illustrative Purposes Only. This model is based on current guidance contained in the National Shellfish Sanitation Program Model Ordinance and the *FDA’s Fish and Fishery Products Hazards and Control Guidance*. Keep in mind that this model does not apply to all situations.

Description	Company: ABC Oyster Company																					
	Where Product Is Purchased			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		Intended Use			Intended Consumer	
	From Fisherman	From Fish Farm	From Processor	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Air Packed	ROP*	Raw to be cooked	Raw RTE*	Cooked RTE*	General Public	At Risk Population
Common Name: Oysters (wild) Market Name: Oysters Scientific Name: <i>Crassostrea spp.</i>			√	√				√	√			√	√			√		√	√		√	

*ROP = Reduced Oxygen Packaging

*RTE = Ready-to Eat

Potential Food Safety Hazards: The following list of potential food safety hazards were based on the product description and processing flow diagram associated with the Shucked Oysters. The hazards are ‘potential hazards’ based on recommendations in the *FDA Hazards and Controls Guidance* from Tables 3-3 and 3-4. Since publication of the bound version of the FDA Guidance, progressive updates have been posted on the respective FDA Seafood HACCP websites. Other hazards not covered by the guidance may be relevant to certain products under certain circumstances.

The FDA recommendations indicate 7 potential hazards that are species- or process-related (FDA Guidance Tables 3-3 and 3-4, respectively). This plan relies on prior controls for the 3 species-related hazards* (Table 3-3; pathogens, natural toxins and environmental chemicals) through tagging by the primary processor or dealer at receiving from the harvest waters. Two of the potential processing hazards (Table 3-4; designed processes and glass inclusion) were not included in the full hazard analysis because this processing operation does not include any special pathogen reduction methods to retain raw product characteristics, and there is no glass exposure in the entire process. The remaining hazards that require control in this secondary operation include:

1. *Pathogens from harvest area (species related, Chapter 4)
2. *Natural toxins from harvest area (species related, Chapter 6)
3. *Environmental chemicals from harvest area (species related, Chapter 9)
4. Pathogenic Bacteria Growth, Temperature Abuse (process-related, chapter 12)
5. Metal Inclusion– (process-related, chapter 20)

SANITATION CONTROL PROCEDURES (SCP) are monitored throughout all processing steps and the daily SCP records accompany the HACCP records.

Hazard Analysis Worksheet

Firm Name <i>ABC Oyster Company</i>	Product Description: <i>Shucked oyster meat</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution: <i>Stored and distributed under refrigeration in tagged containers that are not a reduced oxygen environment</i>
	Intended Use & Consumer: <i>Raw ready-to-eat product that could be eaten raw or cooked by the general public.</i>

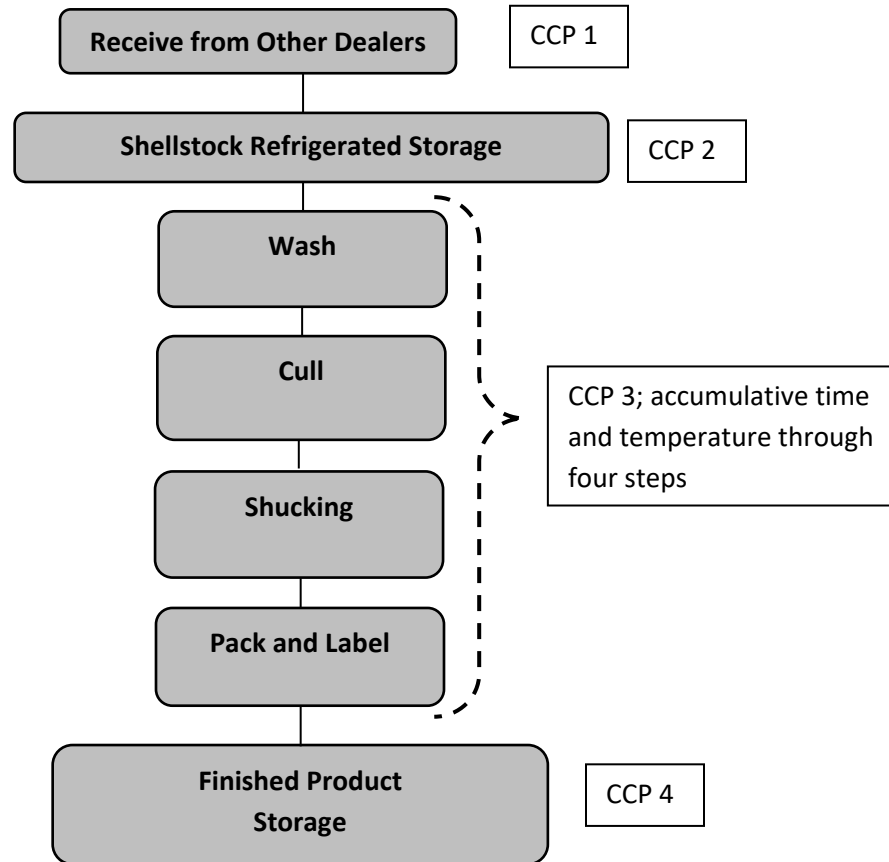
(1) Processing Step	(2) List all potential food safety hazards that could be associated with this product and process.	(3) Is the potential food safety hazard significant (introduced, enhanced or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
Receive oyster shellstock from other Dealers	Pathogens from the harvest area	Yes	Oysters are filter feeders and are likely to accumulate contaminants from the growing area	Only receive properly tagged shellstock harvested from certified dealers.	Yes
	Natural toxins	Yes			
	Environmental chemicals	Yes			
	Pathogenic bacteria growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused during transit	Shellstock loaded onto pre-chilled trucks and temperature controlled during transit	Yes
	Metal Inclusion	No	Not likely to occur at this process step		
Shellstock refrigerated storage	Pathogens from the harvest area	No	Already controlled at the receiving step		
	Natural toxins	No			
	Environmental chemicals	No			
	Pathogenic bacteria growth – temperature abuse	Yes	Pathogens can grow if temperature abused during refrigerated storage	Maintain storage cooler temperature below 45°F/7.2°C	Yes
	Metal Inclusion	No	Not reasonably likely to occur at this processing step		

(1) Processing Step	(2) List all potential food safety hazards that could be associated with this product and process.	(3) Is the potential food safety hazard significant (introduced, enhanced or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
Wash, cull, shuck, pack and label	Pathogens from the harvest area	No	Already controlled at the receiving step		
	Natural toxins	No			
	Environmental chemicals	No			
	Pathogenic bacteria growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Product time-temperature exposure will be monitored	Yes
	Metal Inclusion	No	Not reasonably likely to occur at these process steps		
Finished product storage	Pathogens from the harvest area	No	Already controlled at the receiving step		
	Natural toxins	No			
	Environmental chemicals	No			
	Pathogenic bacteria growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain storage cooler temperature at or below 45°F/7.2°C	Yes
	Metal Inclusion	No	Not reasonably likely to occur at this process step		

Shucked Oyster Meats

Process Flow Chart

(Shaded steps indicate critical control points)



SPECIAL NOTE:

Selection of critical control point parameters based on reference to National Shellfish Sanitation Model Ordinance website; <https://www.fda.gov/media/117080/download>.

HACCP PLAN FORM

Firm Name: <i>ABC Oyster Company</i>	Finished Product Description: <i>Shucked oysters</i>
Firm Address: <i>Anywhere, USA</i>	Method of Storage & Distribution: <i>Stored and distributed under refrigeration in tagged containers that are not a reduced oxygen environment</i>
	Intended Use & Consumer: <i>Raw ready-to-eat product that could be eaten raw or cooked by the general public..</i>

Critical Control Point (CCP)	CCP 1: RECEIVE SHELLSTOCK (Dealer to Dealer)		
Significant Hazard	A) Pathogenic bacteria growth – temperature abuse B) Harvest source (pathogens, natural toxins and environmental chemicals)		
Critical Limits	A-1. Transportation record/documents showing truck prechilled to 45°F (7.2°C) or below prior to loading, and time truck left dealer. A-2. Truck temperature maintained at or below 45°F during transit. [MO Chapter XI. .01 A. (2)]. B-1. Dealer tags contain dealer name, address, and certification number; and harvest date and location, shellstock type and quantity, and required statements. [MO Chapter X. .05] B-2. Dealer must be listed on current FDA Interstate Shellfish Certified Shellfish Shippers List.		
Monitoring	What	A-1. Record of truck pre-chilled and time shipment departed dealer. A-2. Truck temperature maintained at or below 45°F during transit. B-1. Dealers tags with complete information on each container of shellstock. B-2. Dealer certification status per current Shippers List	
	How	A-1. Visual check of truck pre-chilling documents and time departed dealer; A-2. Visual check of truck temperature records during transit; A-3. Visual check of dealer tags per container of shellstock; A-4. Check current dealer listing on FDA Shippers List	
	When	Every delivery, every container	
	Who	Receiving Manager	
Corrective Action	IF container is untagged, THEN reject container; IF truck ambient temperature during receipt is > 45°F, either reject shipment OR check internal temperature of shellstock. IF internal temperature of shellstock meats are above 50°F (10°C) THEN reject shipment; AND contact dealer and discontinue use of dealer until tagging or temperature controls during transit practices have changed.		
Verifications	Monthly check of ambient truck temperature Weekly review of monitoring and corrective action records Review verification records within reasonable time Daily accuracy checks of thermometer and weekly calibration of facility thermometer Accuracy and calibration of truck thermometer per manufacturer’s directions Maintain current Shellstock Shippers List		
Records	Shellfish Receiving Log; truck temperature log record Accuracy and calibration logs Truck pre-chilling record Corrective Action Records		

Signature:	Date:
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HACCP PLAN FORM

Firm Name: <i>ABC Oyster Company</i>	Finished Product Description: <i>Shucked oysters</i>
Firm Address: <i>Anywhere, USA</i>	Method of Storage & Distribution: <i>Stored and distributed under refrigeration in tagged containers that are not a reduced oxygen environment</i>
	Intended Use & Consumer: <i>Raw ready-to-eat product that could be eaten raw or cooked by the general public.</i>

Critical Control Point (CCP)	CCP 2: SHELLSTOCK Refrigerated Storage [MO Chapter XI .01 B. (2)]								
Significant Hazard	Pathogenic bacteria growth – temperature abuse								
Critical Limits	Cooler temperature less than or equal to 45°F/7.2°C [MO Chapter XI .01 B. (2)].								
Monitoring	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; padding: 5px;">What</td> <td style="padding: 5px;">Cooler temperature</td> </tr> <tr> <td style="padding: 5px;">How</td> <td style="padding: 5px;">Continuous temperature recording device.</td> </tr> <tr> <td style="padding: 5px;">When</td> <td style="padding: 5px;">Continuous monitoring by device with visual check once per day.</td> </tr> <tr> <td style="padding: 5px;">Who</td> <td style="padding: 5px;">Cooler Manager</td> </tr> </table>	What	Cooler temperature	How	Continuous temperature recording device.	When	Continuous monitoring by device with visual check once per day.	Who	Cooler Manager
What	Cooler temperature								
How	Continuous temperature recording device.								
When	Continuous monitoring by device with visual check once per day.								
Who	Cooler Manager								
Corrective Action	<p>IF cooler temperature exceeds 45°F; THEN evaluate product safety by determining cumulative exposure temperature and time above 45°F/7.2°C:</p> <p>IF meats are 50°F or less, THEN move product to another cooler OR ice</p> <p>IF internal temperature of shellstock meats are above 50°F (10°C) THEN destroy product AND adjust or repair cooler as necessary.</p>								
Verifications	<p>Weekly review of monitoring and corrective action records</p> <p>Review verification records within reasonable time</p> <p>Check accuracy of temperature recorder and thermometer prior to use daily; Calibrate as directed by manufacturer.</p>								
Records	<p>Temperature Recording Chart and Daily Cooler Log</p> <p>Corrective Action Records</p> <p>Cooler and Thermometer accuracy check and calibration log</p>								

Signature:	Date:
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HACCP PLAN FORM

Firm Name: <i>ABC Oyster Company</i>	Finished Product Description: <i>Shucked oysters</i>
Firm Address: <i>Anywhere, USA</i>	Method of Storage & Distribution: <i>Stored and distributed under refrigeration in tagged containers that are not a reduced oxygen environment</i>
	Intended Use & Consumer: <i>Raw ready-to-eat product that could be eaten raw or cooked by the general public.</i>

Critical Control Point (CCP)	**CCP 3: PROCESSING – WASH, CULL, SHUCK, PACK AND LABEL [Reference MO Chapter XI .01 D (2)]
Significant Hazard	Pathogenic bacteria growth – temperature abuse
Critical Limits	Shucked meats are chilled to an internal temperature of 45°F/7.2°C or less within four hours of removal from refrigeration. [MO Chapter XI. .01 D]
Monitoring	What 1. Processing time 2. Temperature of shucked meat
	How 1. Visual check of clock/timer for start and end time 2. Thermometer
	When Each lot during processing day
	Who Processing Manager
Corrective Action	IF the CL for time is not met (> 4 hours); THEN segregate affected lots and measure meat temperatures. IF > 45°F/7.2°C, destroy product IF the CL for meat temperature is not met at 4 hours, destroy product AND reevaluate shucking process and retrain as needed
Verifications	Weekly review of monitoring and corrective action records Review verification records within reasonable time Check accuracy of thermometer daily and calibrate weekly. Reassess HACCP plan yearly
Records	Shucking Room Time - Temperature Log Corrective Action Records Thermometer accuracy check and calibration log

**This CCP may be eliminated if the company is able to validate that the processing time (oysters outside of refrigeration) is significantly shorter than the required 4 hours from removing the shellstock from refrigeration to a shucked meat temperature of 45°F/7.2°C.

Signature:	Date:
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HACCP PLAN FORM

Firm Name: <i>ABC Oyster Company</i>	Finished Product Description: <i>Shucked oysters</i>
Firm Address: <i>Anywhere, USA</i>	Method of Storage & Distribution: <i>Stored and distributed under refrigeration in tagged containers that are not a reduced oxygen environment</i>
	Intended Use & Consumer: <i>Raw ready-to-eat product that could be eaten raw or cooked by the general public..</i>

Critical Control Point (CCP)	CCP 4: FINISHED PRODUCT STORAGE [MO Chapter XI .01 E]
Significant Hazard	Pathogen growth – temperature abuse
Critical Limits	All containers of shucked oysters are stored, refrigerated ≤ 45°F. [MO Chapter XI. .01 E].
Monitoring	What Continuous temperature recording device.
	How Continuous monitoring by device with visual check once per day.
	When At the beginning and end of the day
	Who Cooler Manager
Corrective Action	<p>IF cooler temperature > 45°F but containers completely surrounded and buried in ice, move containers to another cooler.</p> <p>IF cooler temperature > 45°F and ice inadequate, check temperature of meats. IF meat temperature is above 45°F/7.2°C, destroy product: IF the meat temperature is < 45°F, re-ice and move to another cooler.</p> <p>AND adjust or repair cooler or retrain as necessary.</p>
Verifications	<p>Weekly review of monitoring and corrective action records</p> <p>Review verification records within reasonable time</p> <p>Check accuracy of cooler temperature recorder and thermometer prior to use daily; and calibrate thermometer weekly and cooler as directed by manufacturer.</p> <p>Reassess HACCP plan yearly</p>
Records	<p>Daily Cooler Log</p> <p>Thermometer accuracy check and calibration log</p> <p>Corrective Action Records</p>

Signature:	Date:
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HACCP Plan Form (*landscape format*)

Firm Name <i>ABC Oyster Company</i>	Product Description <i>Shucked oysters</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed under refrigeration in tagged containers that are not a reduced oxygen environment</i>
	Intended Use & Consumer <i>Raw ready-to-eat product that could be eaten raw or cooked by the general public.</i>

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verifications	Records
			What	How	When	Who			
CCP 1: Receive Shellstock (Dealer to Dealer)	A Pathogenic bacteria growth – temperature abuse B Harvest source (pathogens, natural toxins and environmental chemicals)	A-1. Transportation record/documents showing truck prechilled to 45°F (7.2°C) or below prior to loading, and time truck left dealer. A-2. Truck temperature maintained at or below 45°F during transit. [MO Chapter XI. .01 A. (2)]. B-1. Dealer tags contain dealer name, address, and certification number; and harvest date and location, shellstock type and quantity, and required statements. [MO Chapter X.. 05] B-2. Dealer must be listed on current FDA	A-1. Record of truck pre-chilled and time shipment departed dealer. A-2. Truck temperature maintained at or below 45°F during transit. B-1. Dealers tags with complete information on each container of shellstock. B-2. Dealer certification status per current Shippers List	A-1. Visual check of truck pre-chilling documents and time departed dealer. A-2. Visual check of truck temperature records during transit. B-1. Visual check of dealer tags per container of shellstock. B-2. Check current dealer listing on FDA Shippers List.	Every delivery, every container	Receiving Manager	IF container is untagged, THEN reject container; IF truck ambient temperature during receipt is > 45°F, either reject shipment OR check internal temperature of shellstock. IF internal temperature of shellstock meats are above 50°F (10°C) THEN reject shipment; AND contact dealer and discontinue use of dealer until tagging or temperature control during transit practices have changed.	Monthly check of ambient truck temperature Weekly review of monitoring and corrective action records Review verification records within reasonable time Daily accuracy checks of thermometer and weekly calibration of facility thermometer Accuracy and calibration of truck thermometer per manufacturer's directions	Shellfish Receiving Log; truck temperature log record Accuracy and calibration logs Truck pre-chilling record Corrective Action Records

		Interstate Shellfish Certified Shellfish Shippers List.						Maintain current Shellstock Shippers List	
<p>CCP 2: Shellstock Refrigerated Storage [MO Chapter XI .01 B. (2)]</p>	Pathogenic bacteria growth – temperature abuse	Cooler temperature less than or equal to 45°F/7.2°C [MO Chapter XI .01 B. (2)].	Cooler temperature	Continuous temperature recording device.	Continuous monitoring by device with visual check once per day.	Cooler Manager	<p>IF cooler temperature exceeds 45°F; THEN evaluate product safety by determining cumulative exposure temperature and time above 45°F/7.2°C:</p> <p>IF meats are 50°F or less, THEN move product to another cooler OR ice</p> <p>IF internal temperature of shellstock meats are above 50°F (10°C) THEN destroy product</p> <p>AND adjust or repair cooler as necessary.</p>	<p>Weekly review of monitoring and corrective action records</p> <p>Review verification records within reasonable time</p> <p>Check accuracy of temperature recorder and thermometer prior to use daily; Calibrate as directed by manufacturer.</p>	<p>Temperature Recording Chart and Daily Cooler Log</p> <p>Corrective Action Records</p> <p>Cooler and Thermometer accuracy check and calibration log</p>
<p>**CCP 3: Processing —Wash, Cull Shuck, Pack and Label [Reference MO Chapter XI .01 D (2)]</p>	Pathogenic bacteria growth – temperature abuse	Shucked meats are chilled to an internal temperature of 45°F/7.2°C or less within four hours of removal from refrigeration [MO Chapter XI .01 D.]	<p>1. Processing time</p> <p>2. Temperature of shucked meat</p>	<p>1. Visual check of clock/timer for start and end time</p> <p>2. Thermometer</p>	Each lot during processing day	Processing Manager	<p>IF the CL for time is not met (> 4 hours); THEN segregate affected lots and measure meat temperatures.</p> <p>IF > 45°F/7.2°C, destroy product</p> <p>IF the CL for meat temperature is not met at 4 hours, destroy product</p> <p>AND reevaluate shucking process and retrain as needed</p>	<p>Weekly review of monitoring and corrective action records</p> <p>Review verification records within reasonable time</p> <p>Check accuracy of thermometer daily and calibrate weekly.</p> <p>Reassess HACCP plan yearly</p>	<p>Shucking Room Time - Temperature Log</p> <p>Corrective Action Records</p> <p>Thermometer accuracy check and calibration log</p>

**This CCP may be eliminated if the company is able to validate that the processing time (oysters outside of refrigeration) is significantly shorter than the required 4 hours from removing the shellstock from refrigeration to a shucked meat temperature of 45°F/7.2°C.

<p>CCP 4: FINISHED PRODUCT STORAGE [Reference MO Chapter XI .01 E]</p>	<p>Pathogen growth – temperature abuse</p>	<p>All containers of shucked oysters are stored, refrigerated ≤ 45°F. [MO Chapter XI. .01 E.]</p>	<p>Continuous temperature recording device.</p>	<p>Continuous monitoring by device with visual check once per day.</p>	<p>At the beginning and end of the day</p>	<p>Cooler Manager</p>	<p>IF cooler temperature > 45°F but containers completely surrounded and buried in ice, move containers to another cooler.</p> <p>IF cooler temperature > 45°F and ice inadequate, check temperature of meats. IF meat temperature is above 45°F/7.2°C, destroy product: IF the meat temperature is < 45°F, re-ice and move to another cooler.</p> <p>AND adjust or repair cooler or retrain as necessary.</p>	<p>Weekly review of monitoring and corrective action records</p> <p>Review verification records within reasonable time</p> <p>Check accuracy of cooler temperature recorder and thermometer prior to use daily; and calibrate thermometer weekly and cooler as directed by manufacturer.</p> <p>Reassess HACCP plan yearly</p>	<p>Daily Cooler Log</p> <p>Thermometer accuracy check and calibration log</p> <p>Corrective Action Records</p>
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<p>Signature:</p>	<p>Date:</p>
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