

Oysters, raw

Generic HACCP Plan

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1. Process Description

Live Chesapeake Bay oysters are received from harvesters sacked and tagged. Shellstock are delivered to the processing facility within 24 hours of harvesting.

Upon delivery to the processing facility, the shellstock is refrigerated at 45°F until shucked. This is dry storage. Oysters may be kept several days before shucking. Shellstock is placed on tables for hand shucking into buckets. Buckets of shucked oyster meat are given to the packing room for washing, draining and placing into containers. Shucked meats are stored at 40°F.

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2. Flow Diagram

Receiving Live Oysters 	Oysters are received from harvesters sacked and tagged and are delivered to the processing facility within 24 hours of harvesting.
Dry Cooler Storage 	Shellstock are refrigerated at a temperature at or below 45°F (7.2°C).
Shucking 	
Washing/Draining 	
Packing 	
Shucked Oyster Storage 	Storage at or below 40°F (4.4°C)

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3. Potential Hazards

1. **Potential species-related hazards for aquacultured oysters:** (FDA's Fish and Fisheries Products Hazards and Controls Guide: Second Edition)
 - a. Pathogens from the harvest area
 - b. Natural toxins
 - c. Environmental chemical contaminants and pesticides
2. **Potential process-related hazards for aquacultured oysters:** (FDA's Fish and Fisheries Products Hazards and Controls Guide: Second Edition)
 - a. Pathogen growth and toxin formation (other than *Clostridium botulinum*) as a result of time/temperature abuse
 - b. Food and color additives
 - c. Metal inclusion

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4. Hazard Analysis Worksheet

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What control measures can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving Live Oysters	BIOLOGICAL Bacterial pathogens contamination	Yes	Oysters are assumed to be eaten raw. Oysters are easily contaminated with pathogens from harvesting waters	Only accept shellstock from waters open to harvest. Require proper tagging. Require proper harvester license.	Yes
	CHEMICAL Chemical contamination	Yes	Industrial pollution frequently occurs in estuarine waters. Oysters may become contaminated with these pollutants.	Only accept shellstock from waters open to harvest. Require proper tagging. Require proper harvester license.	Yes
	CHEMICAL Natural toxins	Yes	Natural toxins and organisms that produce them can be filtered and concentrated by oysters.	Only accept shellstock from waters open to harvest. Require proper tagging. Require proper harvester license.	Yes
	PHYSICAL None				
Dry Cooler Storage	BIOLOGICAL Bacterial pathogen growth	Yes	Pathogens may increase in number if oysters are not properly cooled during storage.	Maintain coolers at temperatures below 45°F.	Yes
	CHEMICAL None				
	PHYSICAL None				
Shucking	BIOLOGICAL Bacterial pathogen growth	Yes	Excessive time in shucking room can promote pathogen growth	Cumulative time of exposure to ambient temperature is monitored at shucked oyster storage	No
	CHEMICAL None				
	PHYSICAL Bits of shell	No	Hazard analysis indicates that this inherent defect is not "reasonably likely" to result in the food being unsafe for consumption		
	PHYSICAL Metal fragments	No	Not reasonably likely to occur		
Washing/Draining	BIOLOGICAL Bacterial pathogen growth	Yes	Excessive time at washing/draining can promote pathogen growth	Cumulative time of exposure is being controlled at shucked oyster storage	No
	CHEMICAL None				
	PHYSICAL None				
Packing	BIOLOGICAL Bacterial pathogen growth	No	Excessive time at packing step can promote pathogen growth	Cumulative time of exposure is being controlled at shucked oyster storage	No
	CHEMICAL None				
	PHYSICAL None				
Shucked oyster storage	BIOLOGICAL Bacterial pathogen growth	Yes	Pathogens may increase in number if oysters are not properly cooled during storage	Maintain cooler temperature. Limit the cumulative exposure time of oysters to ambient temperatures.	Yes
	CHEMICAL None				
	PHYSICAL None				
Firm Name: ABC Oyster Co.			Product Description: Shucked oysters in plastic one-gallon containers		
Firm Address: Anywhere, USA			Storage and Distribution: Shipped on ice and refrigerated; stored at retail under refrigeration.		
Signature:			Intended Use and Consumer: Raw consumption		
Date:					

*Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.

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5. HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Receiving live oysters	Chemical contamination, Natural toxins, Pathogens	Harvest area is classified as approved or conditionally approved	Growing area on list of state approved areas	Visual check of shellfish tags	Every lot	Quality control person	Reject	Daily record review	Log of tag monitoring
		Harvest area is in open status	Area not closed by SSCA	Maintain ability to be contacted by SSCA					Log of open status
		Harvester is licensed to harvest in the area	Harvester license	Visual check					Harvest area recorded on production log and on tags
		Harvester is certified.	Harvester tag certification number	Visual check					Log of tag monitoring
		Harvester has properly tagged containers.	Containers	Visual check					Log of tag monitoring
	Vibrio growth prevention	Time since harvest	Time since harvest	Note on tags or sales invoice					Log
Dry cooler storage	Bacterial pathogen growth	Coolers not to exceed 45°F for more than two hours	Cooler temperature	Visual check of continuous thermometer	Every two hours during operation	Quality-control Person	Adjust cooler temperature, hold and evaluate product based on total exposure to abusive temperatures	Daily record review. Thermometer calibration weekly.	Cooler temperature record. Recorder chart.
Shucked oyster storage	Bacterial pathogen growth	Cooler temperature must not exceed 40°F for a time greater than two hours. No more than three hours from removal of product from dry storage cooler to placement in the shucked oyster storage	Cooler temperature. Time from dry storage cooler to shucked oyster storage	Visual checks of continuous thermometer. Check progress of marked product.	Every two hours during operation. Marked product checked twice daily (a.m. and p.m.)	Quality-control Person	Adjust cooler temperature. Hold and evaluate based on time and exposure by competent authority. Ice product and/or return shellstock to cooler; hold and evaluate based on time of exposure.	Daily record review. Weekly thermometer calibration. Weekly recorder calibration.	Cooler temperature record. Product time of exposure log.
Firm Name: ABC Oyster Co.					Product Description: Shucked oysters in one-gallon plastic containers				

Firm Address: Anywhere, USA	Storage and Distribution: Shipped on ice and refrigerated; stored at retail under refrigeration
Signature:	Intended Use and Consumer: Raw consumption
Date:	

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

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