REVISED SEPTEMBER 2017

Commercial Processing Example: Oyster Shellstock

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; searched Aug. 2016) and the FDA's Fish and Fishery Products Hazards and Control Guidance (4th Edition, 2011) and additional information available since the 2011 edition. It was produced by the National Seafood HACCP Alliance (SHA) strictly as an example for training. Keep in mind that this model may not apply to all situations.

Narrative

Company	ABC Oyster Company, Anywhere, USA
Market Name	Oysters (Crassostrea virginica)
Source of Fishery Product	Obtained from harvesters (primary processor).
Describe the Food	Live oysters, referred to as shellstock in this plan
Method of Receiving, Storage and Distribution	Oysters are received from harvesters live, during non-Vibrio control months, in the shell directly from the boat. The containers of shellstock are then refrigerated at 45°F/7.2°C within two (2) hours of receipt by ABC Oyster Company.
Finished Packaging Type	Shellstock, in containers such as bags, boxes or bulk containers
Intended Use and Consumer	Shellstock is 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 directly from the harvest vessel and all containers are tagged. Harvest tags are checked for harvester permit number, harvest area to determine if it is an approved area, product identification and quantity, and the date and time of harvest.

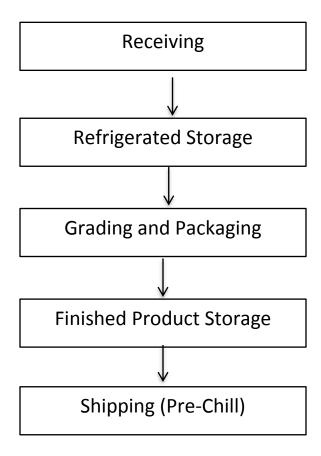
Shellstock refrigerated storage – Containers of shellstock are then immediately placed into refrigerated storage at 45°F/7.2°C until needed for processing.

Grading and Packaging – Shellstock containers are divided up to meet orders. Dealer information is added to the tags on containers.

Finished product refrigerated storage – Containers of shellstock are then immediately placed into refrigerated storage at 45°F/7.2°C until shipped.

Shipping - Shellstock is shipped in refrigerated trucks, prechilled to 45°F/7.2°C or less.

Oyster Shellstock Process Flow Chart



Commercial Processing Example: Oyster Shellstock

Example: For Illustrative Purposes Only. Models are based in current guidance contained in FDA's *Fish and Fishery Products Hazards and Control Guidance*. Keep in mind that this model does not apply to all situations.

DESCRIPTION	DESCRIPTION Company: ABC Oyster Company																					
Elab an		re Pro Purcha	oduct ised	Н	ow Pr Rece	oduct eived	ls	Н	ow Pr Sto	oduct red	ls	Н		oduct ped	ls		ow uct is aged	١	w Prod Will Be	Э		nded sumer
Fish or Shellfish Species	From	From Fish Farm	From Processor	Refrigerated	peol	Frozen	Shelf-Stable	Refrigerated	peol	Frozen	Shelf-Stable	Refrigerated	peol	Frozen	Shelf-Stable	Air Packed	ROP*	Raw to be cooked	Raw RTE*	Cooked RTE*	General Public	At Risk Population
Common Name: Oysters Market Name: Oysters Scientific Name: Crassostrea spp.	1							√				√				√		√	√		V	

^{*}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 oyster shellstock. The hazards are 'potential hazards' based on recommendations in the FDA *Hazards and Controls Guidance* (2011 edition) from Tables 3-3 (species-related hazards) and 3-4 (process-related hazards). 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. Critical control points are established in the National Shellfish Sanitation Program (NSSP) Model Ordinance (searched Aug 2016) and are referenced in the HACCP plan form of this document.

The FDA recommendations indicate 7 potential hazards that are species or process related. Each potential hazard must be addressed in the Hazard Analysis. NOTE: Three of the potential hazards 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 or metal exposure in the entire process.

- 1. Pathogens from the Harvest Area (species-related, chapter 4)
- 2. Natural Toxins (species-related, chapter 6
- 3. Environmental Chemicals (species-related, chapter 11)
- 4. Pathogenic Bacteria Growth, Temperature Abuse (process-related, chapter 12)

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

Hazard Analysis Worksheet

Firm Name ABC Oyster Company	Product Description: Oyster Shellstock, Live, in shell
Firm Location Anywhere USA	Method of Storage & Distribution: Stored and distributed under refrigeration in tagged containers
	Intended Use & Consumer: Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public.

(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)
	Pathogens from the Harvest Area	Yes	Oysters are filter feeders and are likely to accumulate biological contaminants from the growing area	Only receive shellstock harvested from approved waters and properly tagged by a licensed harvester	Yes
Receive oyster	Natural Toxins	Yes	Oysters are filter feeders and are likely to accumulate toxins from the growing area	Only receive shellstock harvested from approved waters and properly tagged by a licensed harvester	Yes
shellstock	Environmental Chemicals	Yes	Oysters are filter feeders and are likely to accumulate chemical contaminants from the growing area	Only receive shellstock harvested from approved waters and properly tagged by a licensed harvester	Yes
	Pathogenic bacteria growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused on the harvest vessel	Control time from harvest to appropriate cooling	Yes
	Pathogens from the Harvest Area	No	Already controlled at the receiving step		
Shellstock refrigerated	Natural Toxins	No	Already controlled at the receiving step		
storage	Environmental Chemicals	No	Already controlled at the receiving step		
	Pathogenic bacteria growth temperature abuse	Yes	Pathogen growth if temperature abused during refrigerated storage	Maintain storage cooler temperature at or below 45° F/7.2° C	Yes

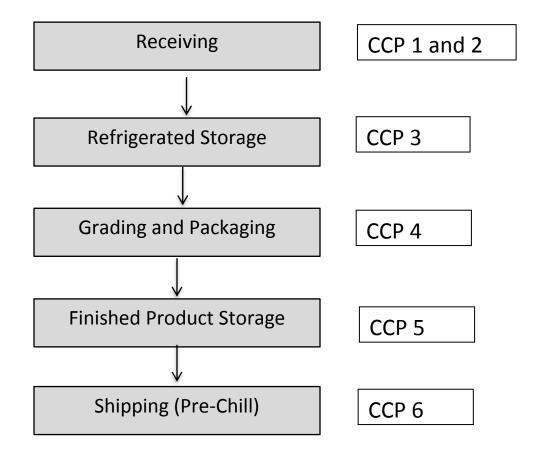
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	T (2)	(5)		(5)	,
(1) Processing Step	(2) List all potential food safety hazards that could be associated with this product and process.	(3) Is the potential food safety hazard significant (introduced, enhanced or eliminated) at this step? (Yes or 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)
	Pathogens from the Harvest Area	No	Already controlled at the receiving step; Additional Dealer tag information controlled at customer receiving		No
Processing –	Natural Toxins	No	Already controlled at the receiving step; Additional Dealer tag information controlled at customer receiving		No
Grading and Packing		No	Already controlled at the receiving step; Additional Dealer tag information controlled at customer receiving		No
	Pathogenic bacteria growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Processing exposure time less than 2 hours	Yes
	Pathogens from the Harvest Area	No	Already controlled at the receiving step		
Finished product	Natural Toxins	No	Already controlled at the receiving step		
storage	Environmental Chemicals	No	Already controlled at the receiving step		
	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
Shipping	Pathogenic bacteria growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Previously refrigerated shellstock loaded on pre-chilled trucks pre-chilled to or below 45°F/7.2°C	Yes

Oyster Shellstock

Process Flow Chart

(Shaded steps indicate critical control points)



Firm Name: ABC Oyster Company	Finished Product Description: Oyster Shellstock
Firm Address: Anywhere, USA	Method of Storage & Distribution: Stored and distributed under refrigeration in tagged containers
	Intended Use: Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public.

Critical Control Point (CCP)		CCP 1: RECEIVE SHELLSTOCK
Significant Hazard		Pathogens, Natural Toxins and/or Chemical Contaminants from the harvest areas
Critical Limits		 Shellfish must be harvested from approved or conditionally approved waters in the open status (NSSP Model Ordinance Chapter XI01 A. (1)(a)) All bags / containers must have a tag that identifies the date and place of harvest, harvester license number, type, and quantity of shellfish (NSSP Model Ordinance Chapter XI01 A. (1)(b)) Harvester must have a valid license (NSSP Model Ordinance Chapter XI01 A.)
What		 Harvest location and status Harvester tag information Harvester license
Monitoring	How	 Check tag information for approved waters from state shellfish control agency. Visual check Visual check
	When	 Every bag or container Every bag or container Every delivery
	Who	Receiving Manager
Corrective Action		IF critical limits violated; THEN, Reject oysters that do not meet all Critical Limit AND To regain control, contact harvester to discuss expectations not being met. If problems continue, then discontinue use of harvesters that are not licensed or do not provide proper tags until license is renewed or tags are corrected.
Verifications		Weekly review of monitoring and corrective action records Weekly check for updates on shellfish harvest water closures or re-openings Annual check that harvest license has been renewed for approved suppliers and check of license status prior to receipt from new suppliers Review verification records within reasonable time Reassess HACCP plan yearly
Records		Shellfish Receiving Log, corrective action records, verification records; training records

Signature:	Date:

Firm Name: ABC Oyster Company	Finished Product Description: Oyster Shellstock
Firm Address: Anywhere, USA	Method of Storage & Distribution: Stored and distributed under refrigeration in tagged containers
	Intended Use & Consumer: Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public.

Critical Control Point (CCP)		CCP 2: RECEIVE SHELLSTOCK
Significant Haz	zard	Pathogenic bacteria growth – temperature abuse
Critical Limits		CL1: Time from harvest initiation to receipt by dealer must meet time to temperature requirements established by the relevant state shellfish control authority based on non-Vibrio control months, based on the Average Monthly Maximum Air Temperature (AMMAT) matrix in the Model Ordinance Chapter VIII @02 A.
		CL2: No more than 2 hours from time of receipt from the boat at loading dock to temperature control
	1	(NSSP Model Ordinance Chapter XIII01 A. (1)(c))
What		Time harvest began Time of receipt Time until temperature control
Monitoring	How	Visual check of tag and clock
	When	Every delivery, every container
	Who	Receiving Manager
Commontive Act		CL1: IF product does not meet time limit, THEN reject product AND speak to harvester about expectations not being met; discontinue use of harvester until harvest practices have changed.
Corrective Action		CL2: If product does not meet time limit THEN destroy product AND reevaluate employee training and/or handling process at receipt
		Weekly review of monitoring and corrective action records
Verifications		Review verification records within reasonable time
Tomounons		State requirements for shellstock time to receipt controls for non-Vibrio months
		Reassess HACCP plan yearly
Records		Shellfish Receiving Log, corrective action records, Verification records; Training Records

Signature:	Date:

Firm Name: ABC Oyster Company	Finished Product Description: Oyster Shellstock
Firm Address: Anywhere, USA	Method of Storage & Distribution: Stored and distributed under refrigeration in tagged containers
	Intended Use & Consumer: Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public.

Critical Control Point (CCP)		CCP 3: SHELLSTOCK REFRIGERATED COOLER STORAGE
Significant Hazard		Pathogenic bacteria growth – temperature abuse
Critical Limits		Cooler temperature less than or equal to 45°/7.2°C (NSSP Model Ordinance Chapter XIII01 B. (2))
	What	Cooler temperature
	How	Continuous temperature recording device
Monitoring	When	Continuous monitoring by device with visual check once per day
	Who	Cooler Manager
Corrective Action		IF cooler temperature exceeds 45°F/7.2°C, THEN check internal temperature of shellstock (edible meats) from throughout cooler. IF oyster meats are 50°F/10°C or less, THEN move product to another cooler or ice properly; AND adjust or repair cooler as necessary. IF internal temperature of shellstock meats are above 50°F (10°C) then destroy product.
Verifications		Weekly review of monitoring and corrective action records Check accuracy of temperature recorder and thermometer prior to use and daily; Calibrate cooler as directed by manufacturer; calibrate thermometer weekly. Review verification records within reasonable time Reassess HACCP plan yearly
Records		Temperature Recording Chart /Daily Cooler Log Thermometer accuracy check and calibration log (verification records) Corrective action records; Training Records

Signature:	Date:

Firm Name: ABC Oyster Company	Finished Product Description: Oyster Shellstock
Firm Address: Anywhere, USA	Method of Storage & Distribution: Stored and distributed under refrigeration in tagged containers
	Intended Use & Consumer: Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public.

Critical Control Point (CCP)		CCP 4: PROCESSING – Grading and Packaging	
Significant Hazard		Pathogenic bacteria growth – temperature abuse	
Critical Limits		No more than 2 hours out of temperature control (45°F/7.2°C). (NSSP Model Ordinance Chapter XIII01 B. (2)(c.))	
What Tim		Time out of temperature (refrigeration) control	
Monitoring	How	Visual check of time	
Monitoring When		Each lot during processing day	
	Who	Processing Manager	
Corrective Action		IF the CL for time is not met; THEN evaluate product safety by determining cumulative exposure temperature and time above 45°F/7.2°C:	
		IF shellstock internal temperature is 50°F/10°C or less, then move product to cooler OR ice.	
		IF internal temperature of shellstock meats are above 50°F (10°C) THEN destroy product AND retrain and reevaluate processing schedule.	
Verifications		Weekly review of monitoring and corrective action records	
		Review verification records within reasonable time	
		Check accuracy of thermometer daily and calibrate weekly	
Records		Time log, corrective action log, accuracy and calibration logs;	
Necolus		Training records	

Signature:	Date:

Firm Name: ABC Oyster Company	Finished Product Description: Oyster Shellstock
Firm Address: Anywhere, USA	Method of Storage & Distribution: Stored and distributed under refrigeration in tagged containers
	Intended Use & Consumer: Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public.

Critical Control Point (CCP)		CCP 5: FINISHED PRODUCT STORAGE (same as CCP #3)
Significant Hazard		Pathogen growth – temperature abuse
Critical Limits		Containers of oyster shellstock are maintained in cooler at or below 45°F/7.2°C or less
	What	Cooler temperature
Manitavina	How	Continuous temperature recording device
Monitoring When Continuous monitoring		Continuous monitoring by device with visual check once per day
	Who	Cooler Manager
Corrective Action		IF cooler temperature exceeds 45°F/7.2°C, THEN check meat temperatures from throughout cooler. IF oyster internal temperature is 50°F/10°C or less, THEN move product to another cooler or ice properly AND adjust or repair cooler as necessary. IF internal temperature of shellstock meats are above 50°F (10°C) THEN destroy product.
Verifications		Weekly review of monitoring and corrective action records Check accuracy of temperature recorder and thermometer prior to use and daily; Calibrate as directed by manufacturer. Review verification records within reasonable time Reassess HACCP plan yearly
Records		Temperature Recording Chart or Daily Cooler Log Thermometer accuracy check and calibration log (verification records) Corrective action records; Training Records

Signature:	Date:

Firm Name: ABC Oyster Company	Finished Product Description: Oyster Shellstock
Firm Address: Anywhere, USA	Method of Storage & Distribution: Stored and distributed under refrigeration in tagged containers
	Intended Use & Consumer: Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public.

Critical Control Point (CCP)		CCP 6: SHIPPING
Significant Hazard		Pathogenic bacteria growth – temperature abuse
Critical Limits		Ambient temperature of truck must be pre-chilled less than or equal to 45°F (7.2°C) prior to loading refrigerated shellstock (NSSP Model Ordinance Chapter XIII01 D.)
		NOTE: Transit temperature is a CCP monitored at customer receiving
V	What	Truck temperature pre-chilled and maintained at or below 45°F (7.2°C) during transit
Monitoring	How	Visual check of truck temperature
Worldoning	When	Every shipment
	Who	Shipping Manager
Corrective Action		IF truck temperature not pre-chilled and maintained at 45° F (7.2°C) or less, check and correct temperature deviation AND fix cooling unit
Verifications		Accuracy check weekly/calibration of truck thermometer per manufacturer's directions Weekly review of monitoring and corrective action records
		Review verification records within reasonable time
		Reassess HACCP plan yearly
Records		Truck cooling log, Accuracy/calibration log;
		Training Records

Signature:	Date:

HACCP Plan Form (landscape format)

Firm Name ABC Oyster Company	Product Description: Oyster Shellstock	
Firm Location Anywhere USA	Method of Storage & Distribution	
	Intended Use & Consumer Shellstock oysters are a raw ready-to-eat product that could be eaten raw or partially cooked by the general public	

Critical Control	Significant	Critical Limits for each Control		Monite	oring		Corrective Action	Verification	Pagarda
Point (CCP)	Hazard(s)	Measure	What	How	When	Who	Corrective Action	verilication	Records
Receive shellstock	Pathogens, Natural Toxins and/or Chemical Contaminants from the harvest areas	1. Shellfish must be harvested from approved or conditionally approved waters in the open status (NSSP Model Ordinance Chapter XI01 A. (1)(a)) 2. All bags / containers must have a tag that identifies the date and place of harvest, harvester license number, type, and quantity of shellfish (NSSP Model Ordinance Chapter XI01 A. (1)(b)) 3. Harvester must have a valid license (NSSP Model Ordinance Chapter XI01 A.)	Harvest location and status Harvester tag information Harvester license	1. Check tag information for approved waters from state shellfish control agency. 2. Visual check 3. Visual check	Every bag or container Every bag or container Every delivery	Receiving manager	IF critical limits violated; THEN, Reject oysters that do not meet all Critical Limit AND to regain control, contact harvester to discuss expectations not being met. If problems continue, then discontinue use of harvesters that are not licensed or do not provide proper tags until license is renewed or tags are corrected.	Weekly review of monitoring and corrective action records Weekly check for updates on shellfish harvest water closures or reopenings Annual check that harvest license has been renewed for approved suppliers and check of license status prior to receipt from new suppliers Review verification records within reasonable time Reassess HACCP plan yearly	Shellfish Receiving Log, corrective action records, verification records; training records

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who	Corrective Action	vernication	Records
Receive	Pathogenic bacteria growth – temperature abuse	Time from harvest initiation to receipt by dealer must meet time to temperature requirements established by the relevant state shellfish control authority based on non-Vibrio control months, based on the Average Monthly Maximum Air Temperature (AMMAT) matrix in the Model Ordinance Chapter VIII @02 A. (NSSP Model Ordinance Chapter XIII01 A. (1)(c))	Time harvest began Time of receipt	Visual check of tag and clock	Every delivery, every container	Receiving Manager	IF product does not meet time limit, THEN reject product AND speak to harvester about expectations not being met; discontinue use of harvester until harvest practices have changed.	Weekly review of monitoring and corrective action records Review verification records within reasonable time State requirements for shellstock time to receipt controls for non-Vibrio months Reassess HACCP plan yearly	Shellfish Receiving Log, corrective action records, Verification records; Training Records
Refrigerated Cooler Storage	Pathogenic bacteria growth – temperature abuse	Cooler temperature less than or equal to 45°/7.2°C (NSSP Model Ordinance Chapter XIII01 B. (2))	Cooler temperature	Continuous temperature recording device	Continuous monitoring by device with visual check once per day	Cooler manager	IF cooler temperature exceeds 45°F/7.2°C, THEN check internal temperature of shellstock (edible meats) from throughout cooler. IF oyster meats are 50°F/10°C or less, THEN move product to another cooler or ice properly AND adjust or repair cooler as necessary. IF oyster meats are above 50°F/10°C, destroy product.	Weekly review of monitoring and corrective action records Check accuracy of temperature recorder and thermometer prior to use and daily; Calibrate cooler as directed by manufacturer; calibrate thermometer weekly.	Temperature Recording Chart /Daily Cooler Log Thermometer accuracy check and calibration log (verification records) Corrective action records; Training Records

Critical Control	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
Point (CCP)			What	How	When	Who	Corrective Action	verilication	Records
								Review verification records within reasonable time Reassess HACCP plan yearly	
Grading and Packaging	Pathogenic bacteria growth – temperature abuse	No more than 2 hours out of temperature control (45°F/7.2°C). (NSSP Model Ordinance Chapter XIII01 B. (2)(c.))	Timer out of temperature (refrigeration) control	Visual check of time	Each lot during processing days	Processing manager	IF the CL for time is not met; THEN evaluate product safety by determining cumulative exposure temperature and time above 45°F/7.2°C: IF shellstock internal temperature is 50°F/10°C or less, then move product to cooler OR ice. IF shellstock internal temperature is above 50°F/10°C, destroy product. AND retrain and reevaluate processing schedule	Weekly review of monitoring and corrective action records Review verification records within reasonable time Check accuracy of thermometer daily and calibrate weekly	Time log, corrective action log, accuracy and calibration logs; Training records
Finished Product Storage	Pathogen growth – temperature abuse	Containers of oyster shellstock are maintained in cooler at or below 45°F/7.2°C or less	Cooler temperature	Continuous temperature recording device	Continuous monitoring by device with visual check once per day	Cooler Manager	IF cooler temperature exceeds 45°F/7.2°C. THEN evaluate product safety by determining cumulative exposure temperature and time above 45°F/7.2°C AND adjust or repair cooler as necessary. IF cooler temperature exceeds 45°F/7.2°C, THEN check meat temperatures from throughout cooler. IF	Weekly review of monitoring and corrective action records Check accuracy of temperature recorder and thermometer prior to use and daily; Calibrate as directed by manufacturer.	Temperature Recording Chart or Daily Cooler Log Thermometer accuracy check and calibration log (verification records) Corrective action records; Training Records

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who	Corrective Action	Vermoadon	Records
							oyster internal temperature is > 50°F/10°C, THEN destroy product.	Review verification records within reasonable time Reassess HACCP plan yearly	
Shipping (pre-chill)	Pathogenic bacteria growth – temperature abuse	Ambient temperature of truck must be pre-chilled less than or equal to 45° F (7.2° C) prior to loading refrigerated shellstock (NSSP Model Ordinance Chapter XIII01 D.) NOTE: Transit temperature is a CCP monitored at customer receiving	Truck temperature pre-chilled and maintained at or below 45°F (7.2°C) during transit	Visual check of truck temperature	Every shipment	Shipping Managers	IF truck temperature not pre-chilled and maintained at 45° F (7.2° C) or less, check and correct temperature deviation AND fix cooling unit	Accuracy check weekly/calibration of truck thermometer per manufacturer's directions Weekly review of monitoring and corrective action records Review verification records within reasonable time Reassess HACCP plan yearly	Truck cooling log, Accuracy/ calibration log; Training Records

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