Job Aid No. 1: “Tier 1 dealer(s) initiates a recall”

Recall Procedures for Molluscan Shellfish Dealers

(Compliant with 21 CFR Part 7 and 21 CFR Part 123)

Purpose

To provide a standardized process for promptly identifying, removing, and correcting distribution of adulterated or misbranded molluscan shellfish in commerce.

Regulatory Basis

This job aid aligns with:

- **21 CFR Part 7** – Recall Policy
- **21 CFR Part 123** – Seafood HACCP
- **National Shellfish Sanitation Program (NSSP)** Model Ordinance, Chapters II and X

Step 1: Identify the Need for a Recall

Initiate a recall immediately if shellfish:

- Are adulterated (e.g., contamination, temperature abuse, harvesting from closed waters)
- Are misbranded (incorrect or missing tags/labels)
- Are linked to illness, injury, or regulatory notification
- Were distributed in violation of HACCP or NSSP requirements

Sources of recall triggers may include:

- Internal monitoring records
- Customer complaints
- Illness reports
- Regulatory agency notification
- Supplier notification

Step 2: Identify Affected Shellfish

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Use shellfish tags and records to determine:

- Shellfish type and species
- The most precise location of harvest
- Harvest date(s)
- Shipper certification number
- Traceability lot codes or other identifiers
- Quantity produced and distributed

Ensure traceability one step forward and one step back as required under 21 CFR 123.

Step 3:

Stop Distribution

- Immediately cease sale and distribution of affected shellfish.
- Segregate and clearly identify the shellfish as “ON HOLD – RECALL.”
- Prevent further use or shipment.

Step 4: Notify Management and Regulatory Authorities

Reference Job Aid 2

- Notify your state shellfish Authority immediately.
- If directed or appropriate, FDA notification may be required.
- Follow any additional instructions provided by Authority.

Step 5: Notify Consignees (Customers) Recall Notification

Reference Job Aid 3

Promptly notify all customers who received the affected shellfish.

Recall notification must include:

- Shellfish identification details

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- Reason for the recall
- Public health concerns (if applicable)
- Instructions to:
    - Stop sale/use
    - Hold shellfish
    - Return or dispose of shellfish
- Contact information for questions

Document:

- Date and method of notification
- Customer responses to the recall

Step 6: Effectiveness Checks

Verify all customers:

- Received the recall notification
- Took appropriate action (shellfish removed from sale/use)

Methods may include:

- Follow-up calls or emails
- Written confirmation
- On-site verification

Step 7: Control and Disposition of Recalled Shellfish

- Maintain control of recalled shellfish at all times.
- Dispose of or return recalled shellfish based on instructions provided by the Authority.

Document:

- Quantity recovered

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- Method of disposition
- Date and location

Step 8: Root Cause Analysis and Corrective Actions

Conduct an internal review to determine:

- Why the problem occurred
- Whether HACCP controls failed

Implement corrective actions, such as:

- HACCP plan revision
- Employee retraining
- Supplier controls
- Process changes

Document all corrective actions per 21 CFR 123.7.

Step 9: Maintain Recall Records

Maintain recall documentation for review, including:

- Reason for recall
- Shellfish identification
- Distribution records
- Notifications
- Effectiveness checks
- Shellfish disposition
- Corrective actions

Records must be:

- Accurate
- Complete

- Readily available to regulators

Step 10: Recall Termination

- Recall may be terminated only after confirmation that:
    - All reasonable efforts were made to recover the shellfish
    - Regulatory authorities agree the recall is complete
- Retain final recall summary documentation.

Quick Recall Checklist

☐ Distribution stopped
☐ Shellfish identified and segregated
☐ Authorities notified
☐ Customers notified
☐ Effectiveness checks completed
☐ Shellfish disposition documented
☐ Corrective actions implemented
☐ Records maintained

Job Aid No. 2: “Tier 1 dealer(s) develops recall notice and provides to the Authority”

Initiating dealer develops a recall notice and provides it to the Authority

Recalling Dealer (Tier 1):

1. Provide the following key data elements in all recall alert communications:
    a. Dealer name address and phone number
        i. If the dealer is in an NSSP program state, also include the dealer certification number
        ii. If the dealer is in a non-participating state, use only the dealer name, address and phone number
    b. Dealer contact person information
        i. Name of the person at the dealer managing the recall
        ii. Email address of the contact person at the dealer
        iii. Direct phone number
    c. Identify shellfish products involved
        i. Type of shellfish
            1. Oysters
            2. Clams
            3. Mussels
            4. Cockles
            5. Whole or roe on scallops
            6. All or some of the above (specify which types of shellfish)
        ii. Product form
            1. Live shellstock ONLY
            2. Non-live, in-shell products ONLY (processed shellfish with one or both shells present)
            3. Shucked ONLY
            4. All or some combination of the above (specify)
    d. Traceability Lot Code (TLC)
        i. TLC examples –
            1. Lot of in-shell product: one type of container from a single harvest date from a single harvest area
            2. Lot of shellstock: one type of bulk shellstock or container from a single harvest date, from a single harvest area
            3. Lot of shucked shellfish: containers from single shucked date, Sell By or Best if Used By date
            4. Application identifier 10 in GS-128 barcode
    e. Traceability Lot Code Source (if not the original shellfish harvester/processor)
        i. Date of harvest
        ii. Dates of wet storage (if applicable)
        iii. Harvest location from shellfish tag
        iv. Type and quantity of shellstock
    f. Shipping Date or Date Range if multiple shipments are involved

Job Aid No. 2: “Tier 1 dealer(s) develops recall notice and provides to the Authority”

   g. Customer purchase/sales order number(s) if applicable
   h. Quantities shipped (cases, bags, boxes etc)
2. What is the reason for the recall
   a. Suspect foodborne illness
      i. Identify the causative agent if known (e.g. biotoxin, Vibrio etc)
   b. Unapproved source
   c. Illegal harvest
   d. HACCP failure
   e. Adulterated product
3. Has this Recall event been registered with the Authority:
   a. YES or NO
   b. If YES, identify which state(s).
4. Were shellfish involved in this recall shipped to other states:
   a. YES or NO
   b. If YES, list all states
5. Provide instructions on what action(s) receiving dealers must take:
   a. Shellfish they have on hand:
      i. Cease sale, service and distribution of the affected shellfish
      ii. Segregate, dispose, and document disposal of all affected shellfish that remain in inventory, or
      iii. Return shellfish
   b. Shellfish that was further distributed:
      i. Enact company’s recall protocols to alert downstream customers who may have received the shellfish and tell them what to do with any affected shellfish on hand.
      ii. Record the information from downstream customers documenting the final disposition of all the affected shellfish (on hand and further distributed) and provide that information to the recalling dealer.

Job Aid No. 2A “Authority Notifies Receiving States”

Example of a recall notice developed by the principal coordinating Authority to receiving states

SHELLFISH RECALL ALERT NOTICE

DATE ISSUED: 01/10/2026
ISSUED BY: Commonwealth of ABC
AFFECTED SHELLFISH PRODUCT: Live Shellstock Oysters (Lot 2354 ABC)
AFFECTED STATES: ABC, DEF and GHI (3)

ALERT - IMMEDIATE ACTION IS REQUIRED

This is a Recall Alert Notice from the Commonwealth of ABC. The Commonwealth of ABC is supporting a recall of shellstock oysters due to a norovirus illness outbreak associated with aquaculture lease site BB567 in the Bivalve Bay harvest area. XYZ Shellfish Company (ABC 010 SP) has contacted their customers who received boxes of fifty-count live shellstock oysters identified with **Lot 2354 ABC** and instructed them to follow their recall protocols. While this is a voluntary recall, immediate action is required.

Receiving State IMMEDIATE Actions

The identified states above are documented to have received affected recalled shellfish with Lot 2354 ABC. Receiving states must take the following immediate actions:

1. Verify companies in your state have received a recall notice from XYZ Shellfish Company.
2. Verify companies in your state have ceased sale, service, and distribution of the affected shellfish.
3. Verify disposal of all affected shellfish (containers or prepped for service) which remain in inventory.
4. Verify downstream customers who may have received affected shellfish have been alerted.
5. Report recall updates to the producing Authority (Commonwealth of ABC).

Affected Shellfish Information & Distribution Detail

- **Shellfish Product:** Live shellstock oysters
- **Traceability Lot Code:** 2354 ABC
- **Harvest Date:** January 2, 2026
- **Harvest Location:** Aquaculture Lease Site BB567, Bivalve Bay
- **Container Quantity Total:** 20 cases (50 oysters per case)
- **Shipping Date:** January 3, 2026
- **Ship To Customer Detail:**
    1. Burgers and Bivalves: 76 Shellfish Ave., Town123, DEF
    2. Desert Oasis: 900 Dry Desert Way, Town456, GHI

Job Aid No. 2A “Authority Notifies Receiving States”

Reason for Recall

This recall is due to a norovirus illness outbreak attributed to oysters harvested from aquaculture lease site BB567 in Bivalve Bay, ABC. While this recall is voluntary, it is necessary to protect public health.

Authority Contact Information

ABC Department of Health
100 Governor St.
Town789, ABC 12345
Phone: (555) 555-5555
Contact: Sally Quahog
Email: Sally.Quahog@abc.gov

Initiating Dealer Contact Information

XYZ Shellfish Company
999 Governor St.
Town789, ABC 12345
Phone: (555) 555-5556
Contact: Joe Shellfish
Email: JShellfish@XYZ.com

This recall has been reported to the ISSC and FDA as required by federal mandate within the guidelines of the National Shellfish Sanitation Program; the Commonwealth of ABC will continue to work closely with regulatory officials to ensure all affected shellfish is removed from the marketplace in order to protect public health.

and may repack shellstock, in a certified, HACCP approved land-based processing facility for introduction into commerce.**Example of a recall notice developed by the principal coordinating Authority to ISSC**

SHELLFISH RECALL ALERT NOTICE

DATE ISSUED: 01/10/2026
ISSUED BY: Commonwealth of ABC
AFFECTED SHELLFISH PRODUCT: Live Shellstock Oysters (Lot 2354 ABC)
AFFECTED STATES: ABC, DEF and GHI (3)

ALERT - IMMEDIATE ACTION IS REQUIRED

This is a Recall Alert Notice from the Commonwealth of ABC. The Commonwealth of ABC is supporting a recall of shellstock oysters due to a norovirus illness outbreak associated with aquaculture lease site BB567 in the Bivalve Bay harvest area. XYZ Shellfish Company (ABC 010 SP) has contacted their customers who received boxes of fifty-count live shellstock oysters identified with **Lot 2354 ABC** and instructed them to follow their recall protocols. While this is a voluntary recall, immediate action is required.

Receiving State IMMEDIATE Actions

The identified states above are documented to have received affected recalled shellfish with Lot 2354 ABC. Receiving states must take the following immediate actions:

1. Verify companies in your state have received a recall notice from XYZ Shellfish Company.
2. Verify companies in your state have ceased sale, service, and distribution of the affected shellfish.
3. Verify disposal of all affected shellfish (containers or prepped for service) which remain in inventory.
4. Verify downstream customers who may have received affected shellfish have been alerted.
5. Report recall updates to the producing Authority (Commonwealth of ABC).

Affected Shellfish Information & Distribution Detail

- **Shellfish Product:** Live shellstock oysters
- **Traceability Lot Code:** 2354 ABC
- **Harvest Date:** January 2, 2026
- **Harvest Location:** Aquaculture Lease Site BB567, Bivalve Bay
- **Container Quantity Total:** 120 cases (50 oysters per case)
- **Shipping Date:** January 3, 2026

Job Aid No. 2B. “Authority Provides Recall Notice to ISSC”

Reason for Recall

This recall is due to a norovirus illness outbreak attributed to oysters harvested from aquaculture lease site BB567 in Bivalve Bay, ABC. While this recall is voluntary, it is necessary to protect public health.

Authority Contact Information

ABC Department of Health
100 Governor St.
Town 789, ABC 12345
Phone: (555) 555-5555
Contact: Sally Quahog
Email: Sally.Quahog@abc.gov

Initiating Dealer Contact Information

XYZ Shellfish Company
999 Governor Street
Town 789, ABC 12345
Phone: (555) 555-5556
Contact: Joe Shellfish
Email: JShellfish@XYZ.com

This recall has been reported to the ISSC and FDA as required by federal mandate within the guidelines of the National Shellfish Sanitation Program; the Commonwealth of ABC will continue to work closely with regulatory officials to ensure all affected shellfish is removed from the marketplace in order to protect public health.

Job Aid No. 3: “Dealer(s) or Authority will issue an effective recall notification”

Example of a specific recall notice developed by the initiating dealer

SHELLFISH RECALL ALERT NOTICE

DATE ISSUED: 01/10/2026
ISSUED BY: XYZ Shellfish Company
AFFECTED SHELLFISH PRODUCT: Live Shellstock American/Eastern (Lot 2354 ABC)
AFFECTED CUSTOMERS: 6 Total (see list below)

ALERT

This is a Recall Alert Notice from XYZ Shellfish Company (ABC 010 SP) to the customers listed below that according to our traceability records received boxes of fifty-count live shellstock oysters identified with **Lot 2354 ABC.** While this is a voluntary recall, **IMMEDIATE ACTION IS REQUIRED** due to reports of **suspect foodborne illness**.

Customer IMMEDIATE Actions

Your company is documented to have received affected cases of recalled shellfish with Lot 2354 ABC and therefore **MUST** take the following immediate actions:

1. Cease sale, service, and distribution of the affected shellfish.
2. Segregate, dispose, and document disposal of all affected shellfish (cases or prepped for service) which remain in inventory.
3. Enact your company’s recall protocols to alert downstream customers who may have received affected shellfish.
4. Account for inventory on hand of the affected shellfish and report back to XYZ Shellfish by 1/12/26.
5. Communicate to the shellfish authority if your company must initiate a further recall for this affected shellfish.

Affected Shellfish Information & Distribution Detail

- **Shellfish Product:** Live shellstock oysters
- **Traceability Lot Code:** 2354 ABC
- **Harvest Date:** January 2, 2026
- **Harvest Location:** Aquaculture Lease Site BB567
- **Case Quantity Total:** 120 cases (50 oysters per case)
- **Shipping Date:** January 3, 2026
- **Ship To Customer Detail:**
    1. Joe’s Mighty Mussels, ABC - 10 cases – Invoice #1234
    2. Cecil’s Clams & Burger Joint, ABC - 10 cases – Invoice #1235

Job Aid No. 3: “Dealer(s) or Authority will issue an effective recall notification”

3. One Shell, Two Shell Seafood Wholesale, ABC- 30 cases – Invoice #1236
4. Beer, Brine, & Hot Sauces, ABC - 50 cases – Invoice #1237
5. Burgers and Bivalves, DEF - 10 cases – Invoice #1238
6. Desert Oasis, GHI - 10 cases – Invoice #1239

The affected shellfish was distributed within the Commonwealth of ABC and the states of DEF and GHI. Notify your shellfish authority if your company’s traceability records indicate affected shellfish was further distributed to other states.

Reason for Recall

This recall is due to suspect foodborne illnesses which have been reported. While this recall is voluntary, it is necessary to protect your customers and your business. The causative agent(s) of the reported suspect illnesses are currently unknown and are being investigated.

Further Action

If customers call your company to report symptoms of foodborne illness (such as nausea, vomiting, diarrhea, abdominal cramps, or fever) which they suspect developed after consuming the affected shellfish, instruct the customers to report their illness to the ABC Department of Health or their state health department.

Initiating Dealer Contact Information

XYZ Shellfish Company
999 Governor St.
Town789, ABC 12345
Phone: (555) 555-5556
Contact: Joe Shellfish
Email: JShellfish@XYZ.com

This recall has been reported to the ABC State Shellfish Authority as required by federal mandate within the guidelines of the National Shellfish Sanitation Program; XYZ Shellfish Company will continue to work closely with regulatory officials to ensure all affected shellfish is removed from the marketplace in order to protect public health.

Job Aid No. 4: “Initiating dealer(s) contacts customers and verifies”

Shellfish Recall Procedures for Initiating Dealers (Tier 1) to Contact Affected Customers (Tier 2)

(Compliant with 21 CFR Part 7 and 21 CFR Part 123)

Purpose

To provide a standardized process for shellfish dealers to promptly contact customers to notify them of the shipment and receipt of recalled shellfish. This Job Aid is not intended to address any public notifications or press releases the recalling dealer may choose to issue.

Regulatory Basis

This job aid aligns with:

- **21 CFR Part 7** – Recall Policy
- **21 CFR Part 123** – Seafood HACCP
- **National Shellfish Sanitation Program (NSSP)** Model Ordinance (where applicable)

Step 1: Gather Recall Details and Develop Recall Communications

Recall details listed below shall originate from the shellfish harvester/processor that is initiating the recall and shall be included in Recall Communications:

- Are shellfish adulterated (e.g., contamination, temperature abuse, harvesting from closed waters)?
- Are shellfish misbranded (incorrect or missing tags/labels)?
- Are shellfish linked to illness, injury, or regulatory notification?
- Were shellfish distributed in violation of HACCP or NSSP requirements?

Step 2: Identify Affected Shellfish Received & On-Hand Quantities

Use inventory or warehouse management systems to determine:

- Receipt dates and counts for affected shellfish
- Palletization and storage for affected shellfish after receipt

Job Aid No. 4: “Initiating dealer(s) contacts customers and verifies”

- Warehouse locations of affected shellfish
- Number of saleable units (bags, boxes, cases, etc.) on-hand
- Lot codes or other identifiers that are confirmed to be “affected”
- Segregate and clearly identify the on-hand affected shellfish as “ON HOLD – RECALL”
- Immediate cease sale and distribution of affected shellfish still on hand

Ensure traceability one step forward and one step back as required under 21 CFR 123.

Step 3: Identify Affected Shellfish which has Shipped

- Identify shellfish item numbers for affected shellfish
- Calculate the number of saleable units which have been further distributed

Prevent further use, consumption, or shipment.

Step 4: Identify Affected Customers & Gather Customer Contact Information

- Pull shellfish item numbers and customer sales records
- Gather customer contact information to determine best method for customer communications (phone call, email, text message, certified letter, etc.)

Step 5: Notify Customers/Send Customer Recall Notification

Reference Job Aid 3

Promptly notify all customers who received the affected shellfish.

Recall notification must include:

- Shellfish identification details
- Reason for the recall
- Health risk (if applicable)
- Instructions to:
    - Stop sale/use

Job Aid No. 4: “Initiating dealer(s) contacts customers and verifies”

    - Hold shellfish
    - Return or dispose of shellfish
- Contact information for questions

Document:

Reference Job Aid 5 and 5A

- Date and method of notification
- Customer responses

Step 6: Notify Shellfish Authority (if applicable)

- Notify your shellfish Authority immediately (email or phone call)
- Follow any additional instructions provided by the shellfish Authority

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Step 7: Control and Disposition of On-hand Recalled Shellfish

- Maintain control of recalled shellfish at all times
- Dispose of or destroy
- Return shellfish for reconditioning, only with regulatory approval
- Document:
    - Quantity recovered
    - Method of disposition
    - Date and location

Step 8: Conduct Supplier Root Cause Analysis and Corrective Actions

Require Suppliers to conduct and submit an internal review to determine:

- Why the problem occurred
- Whether HACCP controls failed

Implement corrective actions, such as:

Job Aid No. 4: “Initiating dealer(s) contacts customers and verifies”

- HACCP plan revision
- Employee retraining
- Supplier controls
- Process changes

Document all corrective actions per 21 CFR 123.7.

Best Practice: Determine accountability of supplier for the recall and decide if purchasing actions must be taken.

Step 9: Conduct Effectiveness Check

Verify all customers:

- Received the recall notification
- Took appropriate action (shellfish removed from sale/use)

Methods may include:

- Follow-up calls or emails
- Written confirmation
- On-site verification (if applicable)

Step 10: Maintain Recall Records

Maintain recall documentation for review, including:

- Reason for recall
- Shellfish identification
- Distribution records
- Notifications
- Effectiveness checks
- Shellfish disposition
- Corrective actions

Job Aid No. 4: “Initiating dealer(s) contacts customers and verifies”

Records must be:

- Accurate
- Complete
- Readily available to regulators

Step 11: Recall Termination

- Recall may be terminated only after confirmation that:
    - All reasonable efforts were made to recover the shellfish
    - State shellfish authority or other regulatory body agrees the recall is complete
- Retain final recall summary documentation

Quick Recall Checklist

☐ Distribution stopped
☐ On-hand shellfish identified and segregated
☐ Shellfish Authority notified
☐ Customers notified
☐ Effectiveness checks completed
☐ Shellfish disposition documented
☐ Supplier corrective actions received
☐ Records maintained

Job Aid 5: Authority Provides Distribution Data

TIER 1 DATA

Initiating Dealer:
Dealer Address:
Certification No.:
Contact Name:
Contact Phone No.:
Contact Email:

Reason for Recall:
Date Recall Initiated:
Recall Notice Provided:

TIER 2 AND TIER 3 DATA

		SHIP-TO CUSTOMER INFORMATION	
Type of Business	**Firm Name**	**Street Address**	**City**

Type of Shellfish (species):
Product Form:
Traceability Lot Code:
Harvest Date:
Wet Store Date:
Harvest Area:

		SHIP-TO CUSTOMER C	
State	**Zip**	**Name**	**Position**

CONTACT INFORMATION					
Phone Number	Email	Date Shipped	Date Received	Invoice No.	Invoice Date

RECALLED SHELLFISH SHIPPED TO CUSTOMER				
Number of Units	Quantity per Unit	Unit Form	Brand Name	Harvest Area

Harvest Date	Wet Store Date	Traceability Lot Code	CONTACT SHIP-TO CUSTOMER			Quantity On Hand
			Date	Time	How	

	RECALLED SHELLFISH STATUS				
Quantity Sold	Quantity Consumed	Customer Contacted	Status of Shellfish	Further Instructions	Final Disposition

Quantity Unaccounted for

Job Aid 5: Authority Provides Distribution Data

TIER 1 DATA

Initiating Dealer: XYZ Shellfish Company
Dealer Address: 999 Governor St. Town789, ABC 12345
Certification No.: ABC 010 SP
Contact Name: Joe Shellfish
Contact Phone No.: 555-555-5556
Contact Email: Jshellfish@XYZ.com

TIER 2 AND TIER 3 DATA

		SHIP-TO CUSTOMER IN
Type of Business	**Firm Name**	**Street Address**
Tier 2: Restaurant	Joe's Mighty Mussels	24 Mussel Ave.
Tier 2: Restaurant	Cecil's Clams & Burger Joint	15 Clam Circle
Tier 2: Shellstock Shipper	One Shell, Two Shell Seafood Wholesale (VA 200 SS)	3 Shell Way
Tier 3: Retail Shop	Shellfish R Us	77 Market St.
Tier 2: Retail Shop	Beer, Brine & Hot Sauces	90 Vendors Ln.
Tier 2: Restaurant/Shucker Packer	Burgers and Bivalves	76 Shellfish Ave.
Tier 3: Retail Shop	Fish 'n Chips	80 Shellfish Ave.
Tier 2: Restaurant	Desert Oasis	900 Dry Desert Way

Reason for Recall: norovirus illness
Date Recall Initiated: 1/10/2026
Recall Notice Provided: YES

Type of Shellfish (species):
Product Form:
Traceability Lot Code:
Harvest Date:
Wet Store Date:
Harvest Area:

FORMATION

City	State	Zip	Name
Town1011	ABC	12346	Joe Mighty
Town1213	ABC	12347	Cecil Smith
Town1415	ABC	12348	Doc Suss
Town1617	JKL	98765	Walt Jones
Town1819	JKL	98764	Heidi Lee
Town123	DEF	67899	Betty White
Towm123	DEF	67899	Sam Clam
Town456	GHI	10112	Sandy Brown

American/Eastern oysters
Live shellstock only
Lot 2354 ABC
1/2/2026
N/A
Lease Site BB567

SHIP-TO CUSTOMER CONTACT INFORMATION				
Position	**Phone Number**	**Email**	**Date Shipped**	**Date Received**
Manager	555-555-1000	Jmighty@mightymussels.com	1/3/2026	1/3/2026
Owner	555-555-2000	cecil@clamsnburgers.com	1/3/2026	1/3/2026
COO	555-555-3000	DocS@1shell2shell.com	1/3/2026	1/3/2026
Owner	666-555-1000	theboss@shellfishrus.com	1/4/2026	1/6/2026
Owner	666-555-2000	heidi@beerbrinehotsauce.com	1/3/2026	1/3/2026
Manager	777-555-1000	Bwhite@BandB.com	1/3/2026	1/5/2026
Manager	777-555-2000	Sam@Fishnchips.com	1/6/2026	1/6/2026
Head Chef	888-555-1000	chef@DO.com	1/3/2026	1/5/2026

RECALLED SHELLFISH SHIPPED TO CUSTOMER					
Invoice No.	Invoice Date	Number of Units	Quantity per Unit	Unit Form	Brand Name
1234	1/3/2026	10	50 oysters	case	Bivalve Blues
1235	1/3/2026	10	50 oysters	case	Bivalve Blues
1236	1/3/2026	30	50 oysters	case	Bivalve Blues
963	1/8/2026	10	50 oysters	case	Bivalve Blues
1237	1/3/2026	50	50 oysters	case	Bivalve Blues
1238	1/3/2026	10	50 oysters	case	Bivalve Blues
647	1/6/2026	5	50 oysters	case	Bivalve Blues
1239	1/3/2026	10	50 oysters	case	Bivalve Blues
		120			

Harvest Area	Harvest Date	Wet Store Date	Traceability Lot Code	CONTACT SHIP-TO CUSTOMER Date	Time	How
BB567	1/2/2026	N/A	2354 ABC	1/10/2026	9:00 AM	phone
BB567	1/2/2026	N/A	2354 ABC	1/10/2026	9:15 AM	phone
BB567	1/2/2026	N/A	2354 ABC	1/10/2026	9:30 AM	phone
BB567	1/2/2026	N/A	2354 ABC	1/11/2026	11:00 AM	email
BB567	1/2/2026	N/A	2354 ABC	1/10/2026	9:45 AM	phone
BB567	1/2/2026	N/A	2354 ABC	1/10/2026	10:00 AM	phone
BB567	1/2/2026	N/A	2354 ABC	1/11/2026	8:00 AM	phone
BB567	1/2/2026	N/A	2354 ABC	1/10/2026	10:15 AM	phone

RECALLED SHELLFISH STATUS				
Quantity On Hand	Quantity Sold	Quantity Consumed	Customer Contacted	Status of Shellfish
8	0	2	YES	held/consumed
10	0	0	YES	held
20	-10	0	YES	held/distributed
6	0	4	YES	held/consumed
50	0	0	YES	held
3	-5	2	YES	held/consumed
2	0	3	YES	held/consumed
10	0	0	YES	held
109	-15	11		

Further Instructions	Final Disposition	Quantity Unaccounted for
destroy remaining 8 cases	8 cases destroyed	0
destroy all 10 cases	10 cases destroyed	0
destroy 20 cases on hand, contact Tier 3 customer and report information back to Tier 1 firm (XYZ)	20 cases destroyed	10
destroy 6 cases on hand, contact retail customers and order destruction, report information back to Tier 2 firm (One Shell, Two Shell)	6 cases destroyed/4 consumed, no ability to contact retail customers	0
destroy all 50 cases	50 cases destroyed	0
destroy all 5 cases on hand, contact retail customers and report information back to Tier 1 firm (XYZ)	3 cases destroyed/2 consumed, contacted customers told to destroy	5
destroy all 2 cases on hand, contact retail customers and report information back to Tier 2 firm (Burgers and Bivalves)	2 cases destroyed/3 consumed, no ability to contact retail customers	0
destroy all 10 cases	10 cases destroyed	0

Job Aid No. 6: “Authority monitors progress and effectiveness of recall”

Recall Procedures for the Shellfish Authority to Monitor a Shellfish Recall

(Compliant with 21 CFR Part 7 and 21 CFR Part 123)

Purpose

To provide a standardized process for shellfish Authorities to monitor the progress and effectiveness of a molluscan shellfish recall.

Definitions

Tier 1: The dealer initiating the recall

Tier 2: Customer(s) that received shipments directly from the Tier 1 dealer

Tier 3: Customer(s) that received shipments directly from the Tier 2 dealer

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Regulatory Basis

This job aid aligns with:

- **21 CFR Part 7** – Recall Policy
- **21 CFR Part 123** – Seafood HACCP
- **National Shellfish Sanitation Program (NSSP)** Model Ordinance, Chapters II and X

Step 1: Provide dealers with a recall data template

Reference Job Aid 5 and 5A

- Immediately after a recall is initiated by the dealer or Authority, the Authority should share the recall data template with all Tier 1 dealers.
- The Authority should communicate directly with the recall coordinator at each Tier 1 dealer and explain how to use the recall data template (recall spreadsheet).
- The Authority should provide the recall data template example to Tier 1 dealers.
- A dealer may choose not to use the recall data template. The Authority must ensure all relevant data are being collected.

Step 2: The Authority establishes a communication schedule with Tier 1 dealers

- Tier 1 dealers should be reporting daily to the recall coordinator for the Authority.

Job Aid No. 6: “Authority monitors progress and effectiveness of recall”

- Reports should include any updates on contacting Tier 2 and 3 customers.
- Reports should include distribution, shellfish status and final disposition.

Step 3: The Authority compiles data (repeat as necessary)

- Data coming from various sources should be compiled by the Authority into one master recall spreadsheet.
- Tier 1 dealers should be compiling Tier 2 customer data.
- Tier 2 customers should be compiling Tier 3 customer data and so on.

Step 4: The Authority communicates with other Authorities (repeat as necessary)

- Contact the recall coordinator identified for Authority(ies) where recalled shellfish have been shipped.
- Provide data specific to their jurisdiction including name, address, contact of dealer(s) receiving shellfish, species, amount, unit type, TLC etc.
- Receive data back from other Authorities and integrate with master recall spreadsheet.

Step 5: The Authority communicates with FDA (repeat as necessary)

- The Authority should share recall data using the recall spreadsheet with their FDA Shellfish Specialist on a daily basis.
- At the termination of the recall, the Authority should send a master recall spreadsheet marked “FINAL”.

Step 6: The Authority writes a final report of the recall

Reference Job Aid 7

- Include relevant information on the date the recall was issued, the Tier 1 dealer information, the type of shellfish, the affected jurisdictions (e.g. states).
- Summarize what happened throughout the recall.
- Provide information on the notification process.
- Provide information on the final disposition of all shellfish.
- Provide report and master recall spreadsheet marked “FINAL” to the FDA Shellfish Specialist.

Job Aid No. 6: “Authority monitors progress and effectiveness of recall”

Quick Recall Checklist

☐ Provide recall data template to dealer(s)
☐ Establish communication schedule with initiating dealer(s)
☐ Compile data daily from all Tier 1 dealers
☐ Communicate with other Authorities about shellfish distribution
☐ Establish communication schedule with FDA Shellfish Specialist
☐ Compile final recall data spreadsheet
☐ Write final report
☐ Share master recall data spreadsheet marked “FINAL” and summary report with FDA Shellfish Specialist

Example of a recall report developed by the principal coordinating Authority for their records and FDA

SHELLFISH RECALL FINAL REPORT

DATE RECALL ISSUED: 01/10/2026
ISSUED BY: XYZ Shellfish Company and The Commonwealth of ABC
AFFECTED SHELLFISH PRODUCT: Live Shellstock Oysters (Lot 2354 ABC)
AFFECTED STATES: ABC, DEF, GHI and JKL (4)

SUMMARY

The Commonwealth of ABC supported a recall of shellstock oysters initiated by XYZ Shellfish Company (ABC 010 SP) on January 10, 2026, due to a norovirus illness outbreak associated with aquaculture lease site BB567 in the Bivalve Bay harvest area with Traceability Lot Code “Lot 2354 ABC” and a harvest date of January 2, 2026. XYZ Shellfish Company contacted their customers who received boxes of 50-count live shellstock oysters identified with Lot 2354 ABC and instructed them to follow their recall protocols. A total of 120 cases of 50-count oysters were shipped to four states (ABC, DEF, GHI and JKL). Product was not wet stored.

NOTIFICATION

XYZ Shellfish Company initiated the recall with their customers on January 10, 2026. They contacted all six customers by phone. Two customers had further distributed product to their customers. Both tertiary customers were contacted on January 11, 2026. All recall information was relayed back to the initiating dealer and provided to the principal coordinating Authority (The Commonwealth of ABC) on a daily basis until the recall was concluded.

The Commonwealth of ABC provided a written recall notification to the ISSC and their FDA shellfish specialist when the recall was initiated on January 10, 2026. The Commonwealth of ABC contacted and provided detailed recall information to the shellfish Authorities in DEF and GHI on January 10, 2026 and the shellfish Authority in JKL on January 11, 2026, when tertiary data were made available. Updates on the recall progress were provided by The Commonwealth of ABC to the FDA on a daily basis until all oysters were accounted for.

FINAL DISPOSITION OF PRODUCT

Of the 120 cases of 50-count oysters from Lot 2354 ABC, 109 cases remained in inventory and were destroyed. Eleven cases were reported consumed, seven of the 11 cases were sold to retail customers. Records did not exist allowing contact of the retail customers. All cases were accounted for by 5pm on January 12, 2026 and the recall was terminated. Please see the attached spreadsheet for detailed recall data.