APPENDIX A

CHECKLIST FOR RECALLS, CLOSURES AND SPECIAL EVENTS

Specific Event: Date of Event:	Date Office Notified:	Date Office Action Initiated:

Task	Staff Initials	Date
Initial shellfish related illness outbreak/hazardous event reported by: Name: Title: Phone: Organization:		
Office Director informed of outbreak/event: ☐ No ☐ Yes		
Food Safety Manager informed of outbreak/ hazardous event: ☐ No ☐ Yes		
Growing Area Manager informed of outbreak hazardous/event: ☐ No ☐ Yes		
Licensing and Certification Manager informed of outbreak/ hazardous event: ☐ No ☐ Yes		
Recall Required: ☐ No ☐ Yes Initiated on date:		
Assistant Secretary informed of outbreak/event: ☐ No ☐ Yes		
Notification to FDA Regional Shellfish Specialist (within 24 hours of Notice): ☐ No ☐ Yes		
Alert to Media ☐ No ☐ Yes (If yes, attach press release)		

Notification to Epidemiology / Public Health Laboratory: (obtain tracking #) Phone: (enter number)

Person Contacted	Tracking Number(s)	Staff Initials	Date

Notification to Local Health Jurisdiction(s) or Tribes (if more space is needed, attach page – Attachment 1)

LHJ /Tribe	Phone #	Person Contacted	Staff Initials	Date
a.				
b.				
c.				
d.				
e.				
f.				

Notification to Receiving State(s) / Country(s) (if more space is needed, attach page – Attachment 2)

State/Country	Phone #	Person Contacted	Staff Initials	Date
a.				

b.				
c.				
d.				
e.				
f.				
Notification of Involved Companies (if more space is needed, attach page – Attachment 3)				
Growers/Dealers				
Company	Phone #	Person Contacted	Staff Initials	Date
a.				
b.				
c.				
d.				
e.				
f.				
Food Safety Investigation				
Item		Person Responsible	Staff Initials	Date
a.	Illness report summary			
b.	Biotoxin Results survey			
c.	Alert Notifications to Retail (Industry List-Serve)			
License & Certification Investigation				
Item		Person Responsible	Staff Initials	Date
a.	Facility Inspection Survey			
b.	Harvest Site Survey			
c.	Recall actions/Report Summary			
d.	Laboratory Sample Submission /Results with EPI/PHL tracking Number			
Growing Area Investigation:				
Item		Person Responsible	Staff Initials	Date
a.	Pollution Source Survey			
b.	Marine Water Quality Results			
c.	Fresh Water Quality Results			
Item		Person Responsible	Staff Initials	Date

Closure Order Actions coordinated with ACO / AAG offices / Assistant Secretary			
Closure Order Issued on date:			
Closure Order Lifted on date:			
Final Report Summary completed			
Distribution of Final Report			
Signature Verifying that all activities for this recall have been completed			Date
ACTION	COMMENTS	Staff Initials	Date

APPENDIX B

(DATE)

(Example Effective Area) Recall Investigation Summary Report

SUMMARY:

Starting at approximately 6 PM on Tuesday (DATE), the operator of the (Example) wastewater treatment plant (WWTP) noted elevated color in the influent and elevated flows from storm inflow and infiltration (I/I). These were occurring due to a rain storm. The plant collected a fecal coliform effluent water sample at 3 p.m. on (DATE) and the result was 'too numerous to count' (TNTC). On (DATE) at 11:20 AM the plant called the department and reported the high result. The operator started injecting chlorine to supplement the normal UV disinfection upon getting the results. The operator stated that all treatment hardware was in good working order and speculated that the TNTC result was due to the elevated color in the influent interfering with UV disinfection. He also reported that influent flows for (DATE) were about 50% above permitted maximum month design flows for the facility. The insufficient disinfection impacted an estimated 1.2 million gallons of sewage in a 48-hr period.

Based on the fecal coliform sample result collected on (DATE) the (EXAMPLE AREA) growing area Conditionally Approved Area Management Plan was implemented and the department closed the Conditionally Approved area for five days from (DATE) until (DATE). Growers were notified of the closure by 12:30 PM on (DATE).

All shellfish products harvested after 12:01AM on (DATE) were recalled. Licensed companies involved were; (EXAMPLE COMPANIES INVOLVED with certification numbers). The two (EXAMPLE COMPANIES) licensed companies did not harvest on that date. (EXAMPLE COMPANY) shipped products to 19 customers in XX State. (EXAMPLE COMPANY) also shipped to 16 customers in 12 other receiving states. A total of 13 states were involved in this recall. All states were notified by email on (DATE) at 9:00 AM via email by the Department of Health.

The amount of (state) product recalled was 3,910 lbs of mussels, 190 lbs of clams and 370 dz oysters. The amount of out of state product recalled was 750 lbs of mussels, 925 lbs of clams and 1,110 dz oysters. Total amount of product recalled was 4,660 lbs of mussels, 1,115 lbs of clams, and 1,480 dz oysters. Out-of-state shellfish products shipped to 11 receiving states have been destroyed by the receiving states. Shellfish products shipped to and located in (state) and (state) have been picked up, returned to the dealer or destroyed on site. Of the shellfish returned back to the dealer, the mussels were destroyed by the dealer at the local landfill and the returned oysters and clams were placed back into wet storage in (EXAMPLE COMPANY).

ILLNESS REPORT SUMMARY:

Not Applicable – no reported illnesses involved.

HARVEST SITE REVIEW:

The source of the product harvested was verified as licensed and certified by the (Authority), as (EXAMPLE COMPANY).

RECALL OF PRODUCT:

Recall of product was initiated Thursday, (DATE) at 12:20 PM following notification by the department. States involved in the recall are listed below:
US States Shellfish Shipments

State	Dealer & Retail company receiving product	Species	Quantity	Product Disposition
Total				

XX State Shellfish Shipments

STATE	Dealer & Retail company receiving product	Species	Quantity	Product Disposition
Total				

GROWING AREA INVESTIGATION:

There was no post-closure shoreline survey.

Water Quality Testing: The (EXAMPLE COMPANY) growing area CAAMP was implemented and the Conditionally Approved area was closed for five days from January 7 (when the TNTC sample was taken). Growers were notified of the closure by 12:30 p.m. on (DATE).

Growing Area Classification Review: Not applicable.

Growing Area Closure: On (DATE) (EXAMPLE COMPANY) growing area was formally closed (e-mail list serve notice); starting (DATE)

Water Quality Results: Not applicable.

SHELLFISH OPERATIONS/FACILITIES INVESTIGATION: Not applicable.

BIOTOXIN MONITORING RESULTS: Not Applicable.

CONCLUSION AND SUMMARY OF ACTIONS:

Recall of Product Confirmation: B & out of state shellfish products recalled.

Reopening of (EXAMPLE) growing area: The (EXAMPLE) growing area was re-opened on (DATE). The 5-Day closure was based on the CAAMP implemented for (EXAMPLE) Growing Area by the department.

Questions should be directed to (EXAMPLE) Point of Contacts.

Name and Title of reporting person and/or State Lead

APPENDIX C

Authority
(Name and Address)
Standard Operating Procedure

1. SUBJECT: Shellfish Recall Program

2. REFERENCES:

   a. Title 21 CFR, Part 7, Enforcement Policy
   b. NSSP 2007 Model Ordinance, Chapter II Risk Assessment and Risk Management
   c. (enter appropriate Authority Rule)

3. PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to provide specific instructions for assigned staff performing a recall of bi-valve molluscan shellfish product.

   3.1 Recalls will be determined based on whether a product's wholesomeness is questioned by:
      a. Pollution events
      b. Biotoxin events/Vibrio parahaemolyticus events
      c. Illness events
      d. Post-harvest contamination

4. PROCEDURES:

   4.1 Establishment of Recall Control:

   Shellfish product recalls are of paramount importance. The Authority will assign a Recall Coordination Lead for each situation involving a shellfish recall. Coordination of support staff needed will be made by the Recall Coordinator. Assigned support staff will be responsive to recall activities and will participate as directed by the Authority. Support staff is expected to accomplish work related to a recall in an expeditious manner and with a great sense of urgency. Recall activities will take priority over normally assigned work. The Authority and Recall Coordination Lead will assure that the following are promptly notified:

   4.2 Notifications:

   4.2. a) The Office Director: This can be in person, by email or telephone with sufficient detail indicating either harvest or post-harvest origin to confirm the need for a recall. With confirmation by the Director, the appropriate Manager and the Recall Coordination Lead will specify the type of recall classification per 21 CFR, Part 7.

   4.2. b) The Assistant Secretary: This can be done in person, by email or by telephone with sufficient detail to provide for awareness of the situation.

   4.2. c) The Growing Area Section Manager: This can be done in person, by email or by telephone with sufficient detail to assist in determining appropriate actions such as closing the growing area, conducting surveys, conducting monitoring, contacting other agencies, tribes and stakeholders, etc. relating to possible growing area closures and investigation of the situation

requiring the recall, such as sanitary or shoreline survey activities, water quality factors, and other environmental factors for consideration.

4.2. d) The appropriate shellfish dealers and/or growers: The industry will be contacted in the most expedient manner concerning recall instructions. The Recall Coordination Lead will organize staff to immediately notify each shellfish grower involved with the recall in person, by email or telephone. The Harvest Site Program Lead will provide involved staff a printed copy of each Dealer/Grower involved in the recall and a clear and detailed script of the recall message to provide to each grower.

4.2. e) The Food and Drug Administration (FDA): This can be in person, by email or telephone within 24 hours with sufficient detail to provide for awareness of the situation. The FDA will be notified of all interstate commerce distribution by providing the list of receiving states and/or foreign countries receiving the product. The FDA will notify foreign countries and non-Interstate Shellfish Sanitation Conference member states upon request by the Office of Shellfish and Water Protection. The Recall Coordinator will provide appropriate Recall Status Reports in accordance with CFR Part 7 to FDA as required.

4.2. f) The Interstate Shellfish Sanitation Conference (ISSC):This can be by email or telephone within 24 hours with sufficient detail to provide for awareness of the situation. The purpose of ISSC notification is for their assistance in notifying all identified receiving states. The FDA will be an addressee on this email for notification of receiving states and/or countries that a potential health risk is associated with recalled shellfish involved with the recall.

4.2. g The Public Health Laboratory (PHL) and Communicable Disease Epidemiology: This can be in person, by email or telephone with sufficient detail to provide for assistance in the tracking or special sampling of illness sources for laboratory support. PHL will assign a tracking number for clinical samples for tracking purposes. Sample collection and submission is coordinated by the Recall Coordination Lead. Samples are tested at the Authority Public Health Laboratory.

4.2. h) The appropriate Local Health Jurisdictions: This can be in person, by email or telephone with sufficient detail to provide for awareness and/or assistance in the recall.

4.2. i) The Recreational Shellfish Program Lead: This can be in person, by email or telephone with sufficient detail to provide for assistance in posting an advisory message on the Program website, coordinating signage with local health jurisdictions, and providing educational materials to local health jurisdictions and other stakeholders.

4.2. j) The Food Safety Program: This can be in person, by email or telephone with sufficient detail to provide for awareness of the situation. The Recall Coordination Lead will notify the appropriate Food Safety Program, of the recall. The Recall Coordination Lead will provide sufficient details to allow the Food Safety Program to determine how best to assist the retail food industry for awareness of the recall and any supportive assistance from local health jurisdictions at the retail level.

4.2. k) The Communications Office: This can be in person, by email or telephone with sufficient detail to provide for awareness of the situation. The Office Director may decide to

issue a News Release announcing a recall. Coordination with the Communications Office will be made prior to any news release. Joint effort will be made with the Communications Office to provide a clear and concise news release providing the details of the situation. The Office Director, Section Manager and Recall Coordination Lead will work closely with the communications staff to develop the news release in a timely manner.

4.3 Recall Activities:

4.3. a) The Recall Coordination Lead will promptly provide information relevant to a recall to the shellfish industry by using the shellfish list serve contact email system and/or by official mail. The recall Coordination Lead will provide sufficient details to ensure clear directions and expectations for Dealer/Growers to provide swift disposition of product within 48 hours to the office.

4.3. b) The Recall Coordination Lead will monitor the progress of the recall and ensure prompt contact with other state agencies, appropriate agencies in other states (with assistance from the ISSC), and the ministries of health or appropriate ministries according to protocol in foreign countries (with assistance from the USFDA), and with shellfish companies involved.

4.3. c) The Recall Coordination Lead will maintain detailed records of the recall, to include records of product destroyed and/or recalled. The Recall Coordination Lead will coordinate with staff in the completion of related recall notification contact forms and other summary reports related to the recall. The Recall Coordinator will maintain all related records when completed on file both in hard copy and electronically on the shared drive.

4.3. d) The Harvest Site Lead will assist in providing the current list of Dealers/Growers involved in the recall. A printed list will be provided to the Recall Coordination Lead and support staff involved in the notification process.

4.3. e) The Recall Coordination Lead will ensure that support staff who are conducting investigation efforts will provide summaries of the review to be added to the final recall summary report. Activities include:

a) Review illness investigation reports
b) Review facility inspection reports
c) Review harvest site applications/information
d) Review Survey of pollution sources
e) Review marine water quality test results
f) Review Biotoxin test results
g) Drafting a summary of growing area findings for pollution, biotoxins, etc. as needed.

4.4 Enforcement:

4.4. a) The Section Manager and Recall Coordination Lead will work with the Enforcement Coordinator, Growing Area staff and Administration support staff in coordination of recall and/or growing area closure orders (if needed) with the ACO/AAG Offices.

4.4. b) The Section Manager and Recall Coordination Lead will coordinate the publishing of an abatement order for any licensed shellfish operations that are involved as to the cause of a recall

with the Section Administrative Assistant (AA) to contact the Adjudicative Service Unit (ASU) for a docket number to identify the order.

4.4. c) The Section Manager and Recall Coordination Lead will coordinate with the Enforcement Coordinator to draft the needed abatement order and will provide the draft to the AA for final preparation and submission to the Office Director for review and approval signature. Upon approval and signature the order will be mailed by certified mail to each grower involved.

4.4. d) The Section Manager and Recall Coordination Lead will coordinate any needed amendment of any abatement order based on situational changes such as re-opening, extensions and/or modifications. The AA will contact the Adjudicative Service Unit (ASU) for a new docket number to identify the changed order. The AA will draft the amended order for final preparation and submission to the Director for review and signature. Upon approval and signature the order will be mailed by certified mail to each grower involved.

4.5 Final Recall Summary Report:

The Recall Coordination Lead will complete the recall summary report. A summary of the details involving the recall will be made and provided to the Office Director upon conclusion of the recall. Each respective element of the recall activities will be described in sufficient detail to provide adequate trace back information and/or account for providing public health protection as a result of the recall. Upon approval of the report, copies will be provided via email and or hard copy to the FDA Regional Shellfish Specialist and other agencies needing the information. Hard copies will be filed according to the office retention schedule and kept electronically on the shared drive under the Recall Program.

5. RELATED FORMS:

a. Authority Checklist for Recall Notification/Events
b. Harvest Site Dealer/Grower list(s)
c. Support Staff Recall Script
d. Investigation Summary Reports (Facility/Growing Area/Laboratory)
e. Recalled Product Disposition Summary Sheets
f. Final Recall Summary Report

6. RELATED DATABASES:

Shared Drive EH/SF/Recall Program

7. AUTHORITY:

Name of SSCA Authority

APPENDIX D

[Insert Name of State] State Licensed Shellfish Company]

RECALL PROCEDURES

Company Name: _____ Certification Number: _____

This recall procedure is to be kept on file by your company in an easily-accessible location.

Should the (Authority) or a Dealer/Grower (Firm) initiate a recall of shellfish product because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the Food and Drug Administration (FDA) and the Authorities in other states if products involved in the recall have been distributed outside of Washington State. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market and issue public warnings if necessary to protect public health. The FDA will decide whether to audit or issue public warnings after consultation with the Authority(s) and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any state involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

The Authority will monitor the progress and success of all recalls within (enter State).

Should there be a need to initiate a recall either by direction of the Authority or by a licensed shellfish company, you are required to adhere to the following:

1. Promptly follow the directions of the Authority in reacting to a recall and/or promptly notify the Authority by telephone when any situations come to your attention which could warrant initiating a recall. These situations could be any reports of illness, biotoxin closures, sewage spills, petroleum products spills, etc.

2. Once informed that a Authority directed recall or a Firm-initiated recall is implemented promptly contact each of your customers by telephone or in person and notify them about the recall. Direct your customers to stop all sales and secure any products involved in the recall that may still be on hand.

3. Properly identify each bag/container of shellstock involved in the recall with an On-Hold for Recall placard or marker with date and separate them from other products not involved in the recall. These recall products must be properly secured.

4. Properly identify each container of shucked meats involved in the recall with an On-Hold for Recall placard or marker with date and separate them from other products not involved in the recall. These recall products must be properly secured.

5. Request that your customers report back to you as soon as possible, but no later than 24 hours, where the recalled products were distributed and whether your customers still have any product on

hand. Maintain an accurate Recall Account Summary Report of products sold to each of your customers and the current disposition of the products:

- Amount sold to each customer during the recall period
- Amount still on hand at your facility
- Amount still on hand at each of your customers facilities
- Amount already sold and consumed and not returnable by each of your customers

6. If there is recalled product, you will instruct your customers to return the product to you for proper securing of it in your facility or to hold it in a separate location at their facility and clearly mark it as not for sale and wait for final disposition instructions.

7. You will promptly notify the Authority as to where the entire recalled product is located. You will coordinate with the Authority or the local health jurisdiction in your area to witness destruction of the product. If required, all product returned to you will be destroyed in the presence of a witness from the Authority or a local or state health jurisdiction, or if approved, you may place shellstock product back in the original growing area on an approved harvest site. You will provide a Recall Account Summary Report of the recalled product to the Authority within 48 hours.

8. A list of your current direct customers and their telephone numbers will be maintained in your records for recall notification.

The Authority contact telephone numbers for recall notification purposes are (enter telephone number) during business hours and (enter telephone number and or pager number) during non-business hours.

The following customer notification list is for your use in contacting your customers.

RECALL CUSTOMER NOTIFICATION LIST

Shellfish Customer	Manager or Contact Person	Phone Number

RECALL SUMMARY ACCOUNT REPORT EXAMPLE

The following Recall Summary Account Report is an example of the information required by the Authority when completing recall notifications. Each company directly involved in distribution of shellfish included in a recall is required to provide this type of summary account report. Reports will be faxed to (enter fax number) and an original copy mailed to the Authority.

EXAMPLE:

Date:
From: Name of Company
Address of Company
Certification Number: i.e. WA-0000-SS
To: State
Attention: Recall Coordinator
Address
Subject: Recall Summary Account Report for (List Area and Date)

Attached is the final Recall Summary Accounting Report for (insert name of company) providing the final disposition of all shellfish products involved and distributed in the recall of (enter date).

Recall Summary Account Report for (enter location and date)					
Product	**Customer Shipped To**	**Quantity Shipped to Customer's Location**	**Quantity Still on hand at Customer's Location**	**Quantity Returned Or Destroyed**	**% Returned Or Destroyed**
Mediterranean Mussels *(pounds)*					
Manila Clams *(pounds)*					
Geoduck Clams *(pounds)*					
Razor Clams *(pounds)*					
Kumamoto Oysters *(dozen)*					
Pacific Oysters *(dozen)*					
Shucked Oyster Meat *(pounds/ounces)*					
Other Species (if applicable)					

Any questions should be directed to (insert name and telephone number of person and email address and fax number).

Signature Block of Company Owner/Manager

APPENDIX E

NAME OF CLOSED GROWING AREA:	
DATE OF CLOSURE:	
REASON FOR CLOSURE:	

CHECKLIST FOR RECALL EVENTS

Growers/Dealers Identified	Person Contacted	Phone Number	Harvest Status	Staff Initials	Date

APPENDIX F

NAME OF CLOSED GROWING AREA:	
DATE OF CLOSURE:	
REASON FOR CLOSURE:	

CHECKLIST FOR RECALL EVENTS

LHJ / Tribe	Person Contacted	Phone Number	Staff Initials	Comments	Date	Time

APPENDIX G

NAME OF CLOSED GROWING AREA:	
DATE OF CLOSURE:	
REASON FOR CLOSURE:	

CHECKLIST FOR RECALL EVENTS

State/Country	Person Contacted	Phone Number	Staff Initials	Comments	Date	Time