.01 Guidance for Investigating an Illness Outbreak and Conducting Recall

A. Requirements for the Authority.

Shellfish are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, from the water column if these organisms are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result. Shellfish can also be contaminated during transport and post harvest treatment; i.e. wet storage, etc. Shellfish can be mishandled during processing which can contribute to the growth of existing microorganisms to the point where consumption can cause illness.

Documentation of the information supporting growing area classification, proper tagging and record keeping, expeditious follow-up on reported illnesses, effective recall of implicated product and public warning announcements are all requisite to protecting public health. Shellfish growing areas implicated through epidemiological association between illness and shellfish consumption must be closed immediately to prevent additional implicated product from reaching the consumer. In addition, shellfish product from the implicated growing areas may be detained and an effective recall of product initiated if the investigation determines that it is necessary to protect public health.

When an illness outbreak investigation indicates that there is an epidemiological association between shellfish consumption and the illnesses, the investigating state Authority shall immediately inform the producing state Authority of the illnesses, the stage of the investigation, and epidemiological link to consumption of molluscan shellfish. Prompt reporting, even in the initial stages of an investigation, will allow the producing state Authority to conduct its investigation (in accordance with Chapter II @ .01 B.) and determine whether harvest area closure, notification, and recall are required.

When an illness outbreak has occurred, immediate closure of the implicated growing area(s) will significantly reduce the chance of additional illnesses during the investigatory process. Immediate closure for the purposes of this guidance document means within 24 hours of notification of the illness (Chapter IV. @03. (A)(1)). If a preliminary investigation reveals that the growing area is not implicated, an immediate closure is not necessary. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Model Ordinance Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* (ISSC/FDA, 2002). Additional information concerning the disease causing potential of shellfish can be found in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* (ISSC/FDA, 2002).

The Authority should assign an Illness Investigation/Recall Coordination Lead (the Lead) for the agency to be listed on the ISSC website as the agency contact person. The Lead will be the agency contact for the duration of the event.

During and after the immediate closure, the Authority must be in the process of investigating, evaluating and conducting increased surveillance. Immediate closures will not always result in an immediate recall of product. It is imperative that the Authority communicate with state epidemiologists, local health officials, pertinent state agencies, industry and others as necessary to complete a thorough investigation.

Additionally, immediate closures may not be necessary if the investigation reveals that the illness outbreak was caused by a specific activity by a single entity which can be controlled through a product recall and an immediate corrective action in the processing or transport of product.

An illness outbreak investigation must include an evaluation of the health hazard presented and consideration of the following factors, including but not limited to:

1. Immediately send staff members out to perform growing area reconnaissance,
2. Review documentation of the information supporting growing area classification, review environmental sample trends, secure additional shellstock and/or water samples if necessary
3. Review toxin sample trends, sampling protocol and supporting information for biotoxin closures, secure additional shellstock and/or water samples if necessary
4. Interview local sources regarding any anecdotal or factual information on the origin of contaminants (large passenger vessels, point and non-point sources),
5. Immediately send staff members out to interview certified dealer(s), restaurant staff members or retail establishment staff members to secure additional details regarding tagging, record keeping, refrigeration temperatures, handling practices, shipping and receiving information and where and from whom the shellfish products were purchased, name and telephone number of contact person,
6. When possible, interview harvesters in the area of concern to determine handling practices and specific harvest area(s)
7. Determine the identity of the product involved, the extent of distribution of implicated product, total amount of the suspected product, total amount in distribution chain, distribution information and proposed recall strategy.

A product recall may not be appropriate when an illness outbreak investigation reveals the following, including but not limited to:

- When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses
- When it has been determined that a specific process conducted by a dealer is the cause of the illnesses

A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market.

When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of product initiated, and the problem immediately corrected. Under these circumstances no closure of the growing waters is warranted in accordance with Model Ordinance, Chapter II, @.01D.

An area which was closed due to an illness outbreak can be reopened using the criteria outlined in the Model Ordinance, Chapter IV @ 03 (A) (5) (c):

> (c) Reopened Status. A growing area temporarily placed in the closed status (as provided in (b) above), shall be returned to the open status only when:

(i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or

(ii) The requirements for biotoxins or conditional area management plans as established in §.04 and §.03, respectively, are met; and

(iii) Supporting information is documented by a written record in the central file.

Whenever an Authority initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, Authorities in other states/countries, ISSC and industry involved in the recall. 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.

Pursuant to the Model Ordinance Chapter II. @ 01 (c) (4) and (D) (2) an Authority initiated recall shall include procedures consistent with The Recall Strategy as provided in 21 CFR Part 7.41, 7.42 and 7.50 as listed below: [for purposes of this guidance "the Authority" will be substituted for "the agency for a Food and Drug Administration"]

FDA will decide whether to audit or issue public warnings after consultation with the Authority(ies), and after taking into account the scope of the product distribution and other related factors. After consultation with the Authority(ies) and after taking into account the scope of the product distribution and other related factors, FDA may audit and/or issue public warnings. If the FDA determines that any Authority involved in the recall fails to implement effective actions to protect public health, the FDA may audit, classify the severity of and publish the recall, including the issuance of public warnings when appropriate.

21 CFR Part 7.41:

Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.
(2)Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
(5) Assessment of the likelihood of occurrence of the hazard.
(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§ 7.42 Recall strategy.

(a) General.

(1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.
(ii) Ease in identifying the product.
(iii) Degree to which the product's deficiency is obvious to the consumer or user.
(iv) Degree to which the product remains unused in the market place.
(v) Continued availability of essential products.

(b) Elements of a recall strategy. A recall strategy will address the following elements regarding the conduct of the recall:

(1) Depth of recall. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or
(ii) Retail level, including any intermediate wholesale level; or
(iii) Wholesale level.

Means of notification, methods of collecting related information, and summary of findings.

Recall notification procedures should be standardized to assure compliance with Title 21 CFR, §7.42:

(2) Public warning. The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or
(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

§ 7.50 Public Notification of Recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm.

Organization of the recall procedures must take into consideration the need for work week, weekend, and holiday notifications. Various recall notification strategies may be used depending on the natureof the illness outbreak and recall. (See attached Appendices and supporting forms for example of a Recall Standard Operating Procedure). Complete removal of shellfish from interstate and intrastate commerce is vital for effective recall reaction. Timely notification and reaction by public health officials utilizing the Title 21 CFR, Part 7 requirements and associated State procedures must provide a safeguard against contaminated shellfish reaching the market. In some cases, duplication of the federal requirements by states may be the method selected to assure standardization of necessary steps to ensure effective recalls.

Educational programs should be developed for both industry and the public describing the public health necessity for effective recall notifications and eliminating potentially unsafe shellfish products from the market place. Programs developed specifically for participation of key industry people may be especially helpful in eliciting cooperative efforts of the entire industry. Such programs should focus on incentives to standardize the procedures for effective and timely recall activities.

The adequacy of state procedures as a basis for assuring rapid and thorough reaction to illness outbreaks and product recall efforts is an important component of this activity. Shellfish recall will be ineffective and/or compromised if State procedures are so written or interpreted that effective reaction can not successfully initiated. It is important that consistent recall expectations and notification procedures be standardized by participating public health Authorities in order to effectively safeguard the general public from potentially hazardous food.

When a recall of shellfish products is initiated, the Authority shall:

1. Immediately notify the appropriate FDA Regional Shellfish Specialist of the recall and provide a recall status report every five (5) working days after the initiation of the recall. Subsequent recall monitoring reports should be provided as information is acquired. The recall monitoring report, which may be verbal or written notification, will include the following information:
    a. The name and address of the recalling dealer(s), plus certification numbers;
    b. The identity of the affected product;
    c. The reason for the recall;
    d. Any other actions deemed appropriate to address the recall such as closing the growing area, conducting surveys, conducting monitoring and contacting other agencies, tribes and stakeholders, in regard to possible growing area closures and investigation of the situation requiring the recall including but not limited to sanitary or shoreline survey activities, water quality factors, and other environmental factors under consideration;
    e. All relevant product identification (harvest date, harvest location, date shucked, lot code, quantity etc.); and
    f. Distribution and redistribution of all shipments of the suspected lots.
2. Establish procedures that ensure support staff members who are conducting investigation efforts will report provide results of the investigation activities to the Lead to be added to the progress updates and 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. Draft a summary of growing area findings for pollution, biotoxins, etc. as needed.

3. Prepare a complete recall summary that determines the effectiveness of the recall. The Authority will forward the recall summary documents to the appropriate FDA Regional Shellfish Specialist within five (5) working days of the completion of the recall. The recall summary will include:
    a. The quantity, type, and status of recalled products returned to or recovered by the recalling dealer(s);
    b. The quantity, type and status (if known) of recalled products not returned to or not recovered by the recalling dealer;
    c. The reason for initiating the recall;
    d. The date the recall was initiated;
    e. The date the recall was completed;
    f. Dealer inspection results or other evidence where appropriate; and
    g. A listing, in chronological order, of any complaints or injuries associated with the product.
    h. Final disposition of all recalled product.
    i. All other actions taken to address the recall 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. Provide a summary of the details involving the recall to the appropriate state authorities 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.

B. Requirements for Dealers.

When an illness has occurred or has been reported to a certified dealer or harvester, they shall immediately notify the Authority. Immediate notification to the appropriate agency will significantly reduce the chance of additional illnesses and will limit the duration and extent of any precautionary growing area closures and product recalls.

The Authority will provide the contact information for the Illness Investigation/Recall Coordination Lead (the Lead) for the agency. The Lead will be the contact for the duration of the event.

The affected industry must cooperate with the Authority during the investigation and evaluation. It is imperative that the industry and the Lead communicate as necessary to complete a thorough investigation.

If the investigation reveals that the source of the illness is found to be the distribution and processing system, shellfish product should be detained and an effective recall of product initiated. The investigation may reveal a problem with the processing of product, if that is the case, the Authority should work with the processor to immediately correct the problem.

Whenever a certified dealer conducts a recall of shellfish products, the dealer shall:

1. Follow the written recall procedures adopted in accordance with Model Ordinance, Chapter X, .03 B.(1) and (2);
2. Immediately notify the Authority which is responsible for the enforcement of shellfish sanitation, unless directed initially by the Authority, that a product recall has been initiated; and
3. Immediately notify the receiving shipper(s) or other receiver/user that a product recall has been initiated;
4. Provide the Authority and the receiver of the product with:
    a. The type and quantity of shellfish being recalled,
    b. The name and license or permit number of each harvester or shipper certification number, as necessary,
    c. The harvest area, and
    d. The date(s) of harvest and shipment as they appear on the shipping tag or invoice;
5. Direct each receiver of the recalled product to examine their receiving records and invoices and report:
    a. The quantity of product received,
    b. The quantity remaining,
    c. The quantity shipped and to whom, including name, address, phone number and date of reshipment, and
    d. All product being held and considered embargoed;
6. Advise the receiver that:
    a. The product is not to be sold or shipped;
    b. Unless advised otherwise by the Authority, the product is to remain on the premises until the Authority representative or other designee arrives;
    c. When appropriate, they should notify their customers who received the product about the recall; and
    d. All receiving and shipping records and invoices for implicated products are to be available for inspection by the Authority's officials.
7. Provide a recall status report to the Lead every five (5)) working days after the initiation of the recall. Subsequent recall monitoring report, which may be verbal or written notification. Unless other wise specified or inappropriate in a given recall case, the recall progress update should contain the following information:
    a. Number of consignees notified of the recall and the date and method of notification;
    b. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received;
    c. Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Authority and the Food and Drug Administration);
    d. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for;
    e. Number and results of effectiveness checks that were made; and
    f. Estimated time frames for completion of the recall.

The dealer must fulfill any additional reporting requirements in accordance with the FD&C Act (21 CFR Parts 7.40-7.59 and 207 FDAAA Section 1005).The recalling dealer has the initial responsibility for determining if the recall is progressing satisfactorily. It is also the obligation of all recalling dealers to determine the effectiveness of their recall. Effectiveness checks aid in verifying that all known, affected consignees received notification about the recall and have taken appropriate action.

C. Requirements for FDA.

Whenever a certified dealer conducts a recall of shellfish products, the FDA Regional Shellfish Specialist shall:

1. Monitor the Authority and FDA actions ensure that the product recall is consistent with the requirements of the NSSP Model Ordinance;
2. Inform other FDA offices as appropriate as new or pertinent recall information from the Authority becomes available; and
3. Coordinate all FDA and other federal assistance provided, as necessary, to affected states.

D. Dispute Resolution.

The ISSC recognizes that states should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish. In instances where prudent action is not taken by a state during recall or illness outbreak situations, an Authority or FDA must notify the Executive Board regarding the state's decision and rationale for taking an action or failure to take an action. The Authority should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that state;
- The potential effect on the public health in other states;
- The potential economic impact on states;
- The necessity for the action within the proposed timeframe

The ISSC will consider the rationale of the Authority and the Executive Board may decide to contact the appropriate agency head or Governor in order to secure prudent public health protection. In the event that action is not taken after deliberation between the Conference and the State, the ISSC may recommend the State as an unresolved issue under the ISSC Constitution, By-Laws and Procedures, Procedure IX. Section 3.

.02 Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak

Because shellfish are filter feeders, they can concentrate microorganisms, marine biotoxins and poisonous or deleterious substances from the water column when these substances are present in the growing area. In addition, shellfish, like any other food product, can become unfit for human consumption through the introduction of contaminants during handling, storage, transport, distribution and processing. Furthermore, improper handling and storage can contribute to the increase of naturally occurring pathogens to hazardous levels in shellfish meats. The intrinsic risk from illness induced by microorganisms associated with consumption of raw or partially cooked shellfish products compels the shellfish control authority to act quickly and effectively when shellfish are implicated in a food-borne outbreak. When illness has occurred, the Authority needs to immediately begin an investigation before critical evidence is inadvertently lost or destroyed.

Currently, the NSSP Model Ordinance does not call for any action if illness is limited to only one person. This is appropriate for molluscan shellfish borne illness caused by microorganisms associated with pollution events. However, when naturally occurring marine bacteria such as *Vibrio vulnificus* or *Vibrio parahaemolyticus* are suspected to cause the illness an evaluation of the possibility of time-temperature abuse of the product is critical to understanding how the illness may have been prevented. A time-temperature audit provides information regarding the time-temperature experience of the product implicated as well as the health conditions of any ill persons which may have contributed to their

susceptibility to the disease. Although the gathering of this data has been a public health focus for several years, there has been no effort to standardize how or what data are gathered during an illness investigation. When naturally occurring marine bacteria are believed to be the source of the shellfish implicated illness or outbreak, the time-temperature history of the product and the health of the persons may be more relevant than the traditional investigatory focus on tracing the origin of the product back to the shellfish growing area.

For additional information concerning the *Vibrio* organisms, see Watkins and McCarthy (1994) and the NSSP Guidance Documents contained within Chapter IV- Naturally Occurring Pathogens.

Time-Temperature Evaluation of a Shellfish Implicated Outbreak

The Authority should promptly conduct an audit of the time-temperature history of the implicated product in a shellfish disease outbreak to the extent practicable. The Authority should use all records from any measuring devices in conveyances or coolers used to transport the product, or any records of conditions associated with the implicated product as it moved from harvest to consumption. Where necessary, the Authority in the state of shellfish product origin should be contacted to provide assistance in gathering information. The audit must include the retail market or restaurant where the victim bought the shellfish product, the facility of the person who sold the product that the retail market or restaurant, the facilities of all dealers and common carriers who handled the product following its harvest, and the practices and facilities of the person who harvested the shellfish. The audit should include, but should not be limited to, the following points.

In the retail market or restaurant implicated in the shellfish illness outbreak, the Authority should, at a minimum,

Record the ambient temperature in the establishment; observe the time-temperature control in the establishment, i.e. how the product was handled:

Examine the establishment's records for the temperature of the storage device or facility used for the implicated product while at the establishment, or observe and record the temperature of the storage device or facility during the investigation; observe and record the temperature and age of the remaining product at the establishment. The age of the product must be cross checked with transaction records;

Observe the controls to prevent cross contamination of the implicated product; and provide for the immediate sampling and testing for the suspect organism(s) of any remaining product from the retail or food service location implicated in the outbreak.

The Authority should determine if the dealer or person who sold the product to the retail market or the restaurant is on the ICSSL. If the person is not on the ICSSL, the Authority should gather any pertinent information regarding the status of time-temperature controls practiced by this person such as:

- Inspection reports for the person's facility;
- Observed temperature of the person's conveyance used to transport shellfish product; and
- Presence or absence of adequate refrigeration capability in the person's conveyance.

If the dealer is on the ICSSL, the Authority should conduct an inspection of the dealer's facility and records for purposes of gathering data from time-temperature control procedures and practices at that facility including:

- The presence or absence of adequate refrigeration capability of the dealer's conveyance;
- The presence or absence of temperature records for the delivery conveyance;
- The observed temperature and time-temperature control practices on the dealer's loading dock;

The transaction records demonstrating the product's age from the date of harvest of the implicated product; and

- The dealer's observed product rotation practice (i.e., the existence of product of widely differing ages).

For additional information concerning the ICSSL, see the NSSP Guidance Document, Chapter III .03: *Dealer Certification and the Interstate Certified Shellfish Shippers List.* The Authority should gather data similar to that above from all dealers or common carriers (certified or uncertified) between the point of first receipt from the harvester and the retail market or restaurant.

The Authority should inspect the original dealer's facility (i.e. the point of first receipt from the harvester). If the original dealer's facility is in another state, the Authority should request the appropriate Authority in that state to perform an audit and to share the results of the audit. This audit should, at a minimum,:

- Determine if there are adequate provisions for product refrigeration;
- Observe temperature and/or records of temperature for the dealer's refrigeration facility;
- Observe general time-temperature control procedures and practices; and
- Observe the temperature and age of shellfish product on-site under receipt from harvesters or under storage.

To the extent practicable, the Authority should gather information concerning the time-temperature control capability of the harvester of record for the implicated product. If the product was harvested in another state, the Authority should request the appropriate Authority in that state to perform an audit and to share the results of the audit. This audit should, at a minimum, determine:

- If adequate shading was provided for harvested shellfish product;
- The existence of mechanical refrigeration for storage of harvested product; and
- If records of prior enforcement actions against the harvester exist.

In cases where *Vibrio* species are the suspected organisms causing the illness or outbreak, the Authority should investigate the health status of the victim(s) to determine:

- If there were underlying health problems which may have contributed to the occurrence of the illness(es);
- If the victim(s) was aware of his underlying condition;
- If the victim(s) was aware of his high-risk status;
- If the victim(s) had been advised not to consume raw shellfish; and
- If the establishment had posted point-of-sale information for high-risk consumers.

References

- Watkins, W. and S. McCarthy. 1994. *Proceedings of the 1994 Vibrio vulnificus Workshop*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-400), Shellfish Sanitation Branch, 200 C Street, SW, Washington, D.C. 175 pages.

Appendices

- Appendix A
- Appendix B
- Appendix C
- Appendix D
- Appendix E
- Appendix F
- Appendix G

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