Proposal No. 2 7 - 2 6 5

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Recall Gudance
10. Specific NSSP Guide Reference	Section IV Guidance Documents, Chapter II, @01
11. Text of Proposal/ Requested Action	

Chapter II. Risk Assessment and Risk Management

@.01 Outbreaks of Shellfish-Related Illness

.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 processing; 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 Authority shall immediately inform the producing 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 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 twenty-four (24) hours of notification of the illness (NSSP Model Ordinance 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 Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* . Additional information concerning the disease causing potential of shellfish can be found in the NSSP Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* .

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~~ determine if a recall is necessary.

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

1. ~~When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses.~~
2. ~~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 NSSP Model Ordinance, Chapter II. @.01 D.

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

1. 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

2. The requirements for biotoxins or conditional area management plans as established in Section .01 and Section .03, respectively, are met; and
3. 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 NSSP 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.~~

~~Assessment of the degree of seriousness of the health hazard to which the~~

~~(4) 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.~~

~~Section 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, Section7.42: (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. Section 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 nature of 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 cannot be 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 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 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 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 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 NSSP 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 otherwise 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 non-responding 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 Food Drug and Cosmetic Act (21 CFR Parts 7.40-7.59 and 207 FDA 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 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:

1. The potential effect on the public health within that State;
2. The potential effect on the public health in other States;

~~3. The potential economic impact on States;~~
~~4. 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 Harvest Area Closure ~~and Recall Notification~~

Chapter II @.01 requires states to provide notification of harvest area closures ~~and recalls~~ to the ISSC. The following forms which include the required information are provided to assist states in complying with notification requirements.

Example Notification

NOTICE OF POTENTIAL HEALTH RISK ASSOCIATED WITH AN IMPLICATED GROWING AREA (Ch II@.01(C)(2))

On **(DATE)**, **(NAME OF AUTHORITY)** determined that an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption existed and began an investigation of the outbreak to determine whether the illness was growing-area related or was the result of post-harvest contamination or mishandling. We have determined that this outbreak is growing-area related and this email serves to notify ISSC and the FDA Shellfish Specialist of these findings.

On **(DATE)**, the **(IMPLICATED HARVEST/GROWING AREA)** was closed to harvest~~ and recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 are being initiated to recall all implicated **(SPECIES)** harvested from **(DATES OF HARVEST)**~~.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

~~**Example Notification**~~

~~**DISTRIBUTION**~~

~~**INFORMATION**~~
~~**RE: PRODUCT RECALL ASSOCIATED WITH OUTBREAK (Ch II@.01(C)(4))**~~

~~On **(DATE)**, **(NAME OF AUTHORITY)** determined an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption, determined that this outbreak is~~

growing area related, and initiated recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 to recall all implicated **(SPECIES)** harvested **from (IMPLICATED HARVEST/GROWING AREA)** from **(DATES OF HARVEST)**. This email serves to provide distribution information to ISSC and FDA.

Recalled product was distributed to dealers and/or retailers in the following states: **(NAME OF EACH STATE)**. In accordance with Ch II@.01(I), we have notified each of the receiving states.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

Distribution information is as follows:

Shipping Dealer #1
Name & ICSSL #:

Harvest Area	**Harvest Date**	**Receiving Dealer, Retailer, or Food Service** *(Include ICSSL #, if known or applicable)*	**City, State**	**Sale Date**	**Lot No. or Date Shucked**	**Qty Sold**	**Product Description**	**Status** *(Consumed, destroyed, returned)*

(include as many tables as needed, depending on number of shipping dealers involved in recall)

Shipping Dealer #2
Name & ICSSL #:

Harvest Area	**Harvest Date**	**Receiving Dealer, Retailer, or Food Service** *(Include ICSSL #, if known/applicable)*	**City, State**	**Sale Date**	**Lot No. or Date Shucked**	**Qty Sold**	**Product Description**	**Status** *(Consumed, destroyed, returned)*

Attachments:

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~~

NOTE: To view, print, or download Appendix A, ~~B, C, D, E, F, or G~~ click on the link below.

Checklists for Recalls, Closures and Special Events

.03. Guidance for Conducting a Recall

The following guidance relies on the Recall Process Flow Chart found in Appendix X. The Recall Process Flow Chart is the parent document to the various job aids presented in Appendices X-X. The Recall Process Flow Chart along with the various job aids and the descriptive text in this section should be used to inform the initiating dealer and Authority of the steps to take to manage a shellfish recall.

Shellfish recalls are an important tool used by shellfish dealers and Authorities to stop the distribution of unsafe shellfish to potentially prevent illnesses. Recalls are guided by the NSSP Model Ordinance and 21 CFR Part 7and are a voluntary action that recognizes the responsibility of dealers to protect public health. An effective recall depends on both the dealer and the Authority understanding the recall process and having an existing plan ready to execute in the event a recall is initiated. Dealers and Authorities must understand the role they play in any recall and be prepared to take appropriate steps quickly to trace and recover as much shellfish product as possible and thereby have the greatest protective effect. Dealers and Authorities are encouraged to conduct mock recall exercises to test their readiness. This guidance includes several job aids that may be used in the event of an actual recall or in a mock shellfish recall.

Both dealers and Authorities should designate an individual as the recall coordinator. This individual should be trained in recall procedures in general and specific recall procedures for their company and industry. For example, the dealer's recall coordinator should know how to access company records to conduct an efficient trace forward. Similarly, the Authority recall coordinator should know what shellfish species their industry deals with and how they generally distribute their products. The Authority recall coordinator should be identified on the ISSC website and the information kept current by each Authority through notification to the ISSC Executive Office. This ensures there is easy access to current contact information for trained

individuals in each member state.

A. Determining if a Recall is Necessary.

The first step in any recall process is determining that a recall of shellfish is necessary (NSSP Chapter II). This determination can be made by a dealer and/or an Authority.

To determine if a recall is necessary the dealer and/or Authority should conduct a health hazard assessment consistent with 21 CFR Part 7.41 and consider:

1. Have any illnesses or injuries occurred from the use of the shellfish?
2. Do conditions exist that will expose humans to a health hazard?
3. What populations are at risk of exposure?
    a. Consider individuals who may be at greatest risk
4. What is the degree of seriousness of the illness or injury?
5. What likelihood exists for the occurrence of the illness or injury?
6. What are the consequences of the illness or injury (immediate or long-range)?

Based on the health hazard assessment, the dealer and/or Authority will determine if a recall is necessary and proceed with the shellfish recall as deemed appropriate. The result of the health hazard assessment answers as to why a recall is or is not initiated.

A shellfish recall may not be appropriate when an illness outbreak investigation reveals any of the following conditions, or others which may not be listed:

1. Source Contamination: when evidence confirms shellfish from a specific location (e.g. a single aquaculture lease site) are the cause of the illnesses/injuries and can be controlled easily and effectively.
2. HACCP Failure: when it is determined a dealer, processor, shipper, or retailer has failed to comply with any component of its Hazard Analysis and Critical Control Plan (HACCP) and shellfish are still within their control
3. Process Correction: when after harvest or processing the cause of potential illness/injury can be corrected and controlled easily and effectively by a firm.
4. Market Access: when it is determined the recalled shellfish are no longer available in the marketplace given reasonable assumptions regarding shelf life and how the shellfish product is intended to be used and stored.

B. Determining the Scope of a Recall.

When the health hazard assessment indicates a recall is necessary, the dealer and/or Authority shall determine what shellfish need to be

recalled. This assessment should be consistent with 21 CFR 7.42 and consider the following:

1. Can the shellfish be identified?
2. How are the shellfish identified?
3. Is the product hazard obvious and easy to explain to users?
4. Does the shellfish remain in the marketplace?
5. Is there continued availability of the shellfish?

Based on this assessment the dealer and/or Authority can identify the shellfish to be recalled using data such as the type of shellfish, form of the shellfish (shellstock, shucked, etc.), the Traceability Lot Code(s) (TLC), harvest date(s), wet storage date(s), harvest location, shipping date(s), ship to locations, and quantities of affected product shipped.

Determining the product dates or TLCs to be recalled should include consideration for:

1. What is the first date affected shellfish reached the marketplace?
2. What is the type of shellfish?
3. What is the intended use of the shellfish?
4. What is the expected shelf life of the product?
5. How likely will an end user not use the shellfish as intended?
6. What is the extent to which end users may not follow the intended use?
7. When will all affected shellfish be out of the marketplace (used, expired, or destroyed)?

A recall justification written by the dealer and/or Authority should include information on all factors considered to determine the date range of the shellfish recall.

C. Conducting a Shellfish Recall.

The Recall Process Flow Chart, identifying the various steps involved in conducting a shellfish recall can be found in Appendix X. This flow chart is the primary reference document for the associated job aids (Appendices X-X) created to assist dealers and Authorities in the event a recall is deemed necessary. These materials are recommended but not required to be used to assure completeness and consistency during a recall.

When a recall is initiated by a dealer, the dealer must immediately inform the Authority. When a recall is initiated by an Authority, the authority will immediately inform the affected dealer or dealers. When using the job aides in Appendices X-X as a reference, dealer(s) who initiate a recall, by their own determination or as directed by the Authority, are considered to be the "initiating dealer(s)." Dealers who initiate a recall have a specific role throughout the recall process to the Authority. The Authority in the jurisdiction of the initiating dealer is considered the principal coordinating Authority(ies) and has a specific role throughout the recall process. If a recall involves multiple shellfish origins, then the FDA should operate as the

principal coordinating authority compiling all data. However, when multi-origin recalls occur, Authorities should continue to share recall information with all other Authorities to maintain efficiency and effectiveness of the recall.

Once a recall is initiated, the initiating dealer(s) begins the recall following their recall procedures. All shellfish dealers are required to have a written recall plan (NSSP Chapter X .03 B.) which have been approved by the Authority.

Job Aid No. 1: Understanding the Recall Process.

- This job aid outlines the steps necessary for a dealer to initiate and complete a recall including the following steps: identifying the need for a recall, identifying affected shellfish, stop product distribution, notifying management and regulatory authorities, notifying customers, conducting effectiveness checks, controlling disposition of recalled shellfish, conducting a root cause analysis and corrective actions, records maintenance, and terminating the recall.

Job Aid No. 2: Developing a Recall Notice.

- This job aid outlines for a dealer that initiates a recall, the information necessary for the recall notice. The initiating dealer must provide key data elements (KDEs) including: the Initiating dealer name, address and phone number, the Initiating dealer contact person, the shellfish involved (product description, type, and form), the shellfish quantities, the Traceability Lot Code (TLC) and Traceability Lot Code Source (TLCS), the shipping date or date range, the reason for the recall, if the recall has been reported to the Authority, if the shellfish have been shipped to other states and what actions receiving dealers must take. It is recommended for all KDEs to be managed using a sortable spreadsheet (See FDA Food Traceability Rule Templates)

Once the recall notice is developed by the initiating dealer and provided to the Authority, the Authority must distribute the information to receiving states, the FDA and the ISSC (NSSP Chapter II).

Job Aid 2A: Authority Recall Alert Notice Template to Other Authorities.

- This job aid is an example of a recall alert notice as developed by the producing state Authority and distributed to receiving states. Included in the recall alert notice are all necessary key data elements (KDEs) for receiving states with specific details on receiving dealers in the receiving states; information should be presented in a sortable spreadsheet for clarity, completeness and consistency. The Authority may decide to post the recall alert notice on their website or use other means of expanding distribution.

The following considerations may be used by the Authority to determine when a recall alert notice is posted to its website or further distributed by more expansive communication protocols:

(i) Is there suitable assurance the shellfish have been effectively removed from commerce?
(ii) Did the dealer send their Recall Notice/Press Release to the Associated Press or other appropriate media outlets?
(iii) Is recall expansion necessary, based on investigation findings and recall effectiveness checks?
(iv) Is there evidence that affected product was commingled with, or transformed into, other lot codes/product by other processors (e.g. wet or dry storage, shellstock to shucked)?

The Authority may choose to assess or reassess posting or further distributing recall alert notices at any point in the recall process.

The Authority must also provide notice to the FDA (NSSP MO) who will then further distribute the recall alert notice internally to State Liaisons, and externally to all NSSP Authorities, and states not yet identified as receiving product, for awareness. The FDA will determine if a public safety alert is warranted to amplify the recall information. FDA will decide whether to audit or issue public safety alert after consultation with the Authority, and after taking into account the scope of the shellfish distribution and other related factors. After consultation with the Authority and after taking into account the scope of the shellfish distribution and other related factors, FDA may audit and/or issue public safety alert. 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 alert notice, including the issuance of public safety warnings when appropriate. The purpose of a public safety alert is to alert the public that shellfish being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled shellfish appear inadequate. The recall strategy will specify whether a public safety alert is needed and whether it will issue as:

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

Job Aid 2B: Template for a Recall Alert Notice from the Authority for ISSC.

- The Authority must provide notice to the ISSC (NSSP MO) who will further distribute the recall alert notice to the membership and post on their website. This job aid is an example recall alert notice developed by the recalling Authority and distributed to ISSC and is similar to 2A, but does not include specific details on receiving dealers, since some state laws and regulations prevent sharing of sensitive information with a third party; individuals coordinating the recall on behalf of the Authority should understand and follow these restrictions. This template is not required to be used by the Authority, but is highly recommended for clarity, completeness and consistency.

Simultaneously with the notifications being distributed by the Authority to receiving states, the FDA and the ISSC, the initiating dealer must issue a

recall alert notice to all affected customers identified from the dealer's shipping critical tracking events (CTE). Receiving customers may include wholesale shellfish dealers, retailers, or direct retail customers. The receiving entities are considered "affected customers" of the initiating dealer and are referred to as "Tier 2" entities in the job aids (Appendices X-X) Tier 2 entities may have a further and specific roles in the recall process.

Job Aid No. 3: Recall Alert Notice developed by the initiating dealer to their affected customers (Tier 2).

- This job aid is an example of a recall alert notice developed by the initiating dealer and distributed to their affected customers (Tier 2). The Recall Alert Notice includes the Initiating dealer name, address and phone number, the Initiating dealer contact person, the shellfish involved (product description, type, and form), the shellfish quantities, the Traceability Lot Code (TLC) and Traceability Lot Code Source (TLCS), the shipping date or date range, the reason for the recall, if the recall has been reported to the Authority, if the shellfish have been shipped to other states and what actions receiving dealers must take. It is recommended for all KDEs to be managed using a sortable spreadsheet (See FDA Food Traceability Rule Templates) key data elements (KDEs).

Job Aid No. 4: Initiating Dealer Contacts Customer to verify receipt of recall alert notice and disposition of the affected shellfish. This job aid frames the entire recall process for the initiating dealer and their affected customers.

- This job aid outlines the steps necessary for an initiating dealer to conduct a recall with their affected customers including: gathering details and developing recall alert notices, identifying affected shellfish received and on-hand quantities, identifying affected shellfish that has shipped, identifying affected customers and getting contact information, notifying customers who received shellfish, notifying the Authority, controlling and disposition of on-hand shellfish, conducting a supplier root cause analysis and corrective actions, conducting an effectiveness check, maintaining recall records, and terminating the recall.

At this point, the initiating dealer has notified all affected customers. The affected customers may have further distributed shellfish and must themselves forward the recall information to their affected customers ("Tier 3"). This trace forward process continues through the distribution chain until it reaches the shellfish end point. All information is sent up the distribution chain through the various dealers/customers.

For example, if the shellfish end point was a retail seafood shop two steps removed from the initiating dealer, that shop would collect their data and provide it to the secondary dealer. The secondary dealer would then provide that information to the initiating dealer. This "roll-up" of recall data allows all the information to be compiled by the initiating dealer. The initiating dealer should provide the data to the Authority as it is received or daily until the recall is terminated.

The Authority where the initiating dealer is located is responsible for managing the recall key data elements. This is a difficult task given the amount of information that may be received by the initiating dealer and is why the FDA expects all key data elements to be transmitted by all affected firms using a sortable spreadsheet (FDA FTR reference).

Job Aid No. 5 and 5A: Recall Key Data Element sortable spreadsheet template and example.

- This job aid is a sortable spreadsheet template to collect recall key data elements and is an example sortable spreadsheet filled out with the recall key data elements provided in Job Aid No. 3. The recall sortable spreadsheet can be used by the initiating dealer to conduct the trace forward and record the recall key data elements or by the Authority to compile all of the key data elements sent by the initiating dealer from the trace forward. This template is not required to be used by the Authority, but is highly recommended for clarity, completeness and consistency. The sooner the sortable spreadsheet is used in the recall process, the easier the collection of key data elements will be complete and communication among the entities involved in the recall will be final. The top of the sortable spreadsheet includes the initiating dealer (Tier 1) key data elements, the reason for the recall and the shellfish information. The table below the initiating dealer data is set up to collect key data elements from their customers (Tier 2) and their subsequent customers (Tier 3 etc.). The instructions for filling out the fields are included on the second tab of the sortable spreadsheet.

In cases of recalls conducted in multiple states, the Authority(ies) in the receiving state(s) may compile the key data elements for their affected firms. Key data elements should be provided to the Authority where the initiating dealer is located and added to the master sortable spreadsheet. Authorities in other states may choose to pass recall KDEs through the FDA but should be aware that federal data sharing limitations may prevent effective exchange of information to other states. Therefore, it is recommended that Authorities share recall KDEs with each other directly and include the FDA as a courtesy. Contact information for individuals responsible for recalls in each member state may be found on the ISSC website. If a non-member state or foreign country is involved in a recall, the Authority can request contact information from the FDA.

Job Aid No. 6: Role of the principal coordinating Authority.

- The Authority where the initiating dealer is located should monitor the progress and effectiveness of the recall. This is best accomplished through regular communication and free sharing of data. Job Aid No. 6 outlines the procedure for an Authority to monitor a shellfish recall including providing dealers with the recall KDE spreadsheet or establishing how KDEs should be collected and provided, establishing communication and a communication schedule,

compiling data into a sortable spreadsheet, communicating with other Authorities, communicating with the FDA, and writing a final report.

Job Aid No. 7: Completing a Final Recall Report.

- This is an example of a final recall report, compiled by the principal coordinating Authority once a recall is terminated. This template is not required to be used by the Authority, but is highly recommended for clarity, completeness and consistency. The final report should include all relevant information related to the recall including an overall summary, the notification and communication process and final disposition of the shellfish.

.04. Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak
.05. Determining the Size of Closed Area as a Result of Illnesses
.06. Dispute Resolution.

The ISSC recognizes that shellfish Authorities 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 an Authority during recalls or illness outbreak situations, an Authority or FDA must notify the Executive Board regarding the Authority'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:

1. The potential effect on public health within that jurisdiction;
2. The potential effect on public health in other jurisdictions;
3. The potential economic impact on jurisdictions; and
4. 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, Governor or other jurisdictional authority to secure prudent public health protection. If action is not taken after deliberation between the ISSC and the Authority, the ISSC may recommend an unresolved issue under the ISSC Constitution, By-Laws and Procedures, Procedure IX. Section 3.

~~**.05. Determining the Harvesting Periods Associated with Implicated Product for Identifying Shellfish to be Included in the Recall**~~

~~A. Identify the harvest date of all reported illness(es).~~
~~B. Determining the likelihood of product remaining in the marketplace with consideration of shellstock vs. in-shell vs. fresh shucked vs. frozen shucked.~~
~~C. Identify the date of [last] most recently reported illness(es) and the date of growing area closure.~~

	~~**.01 Determining the Scope of Implicated Product for Conducting a Recall**~~ ~~A. Are illnesses related to:~~ ~~(1) single harvester~~ ~~(2) single dealer or~~ ~~(3) single route of transportation~~ ~~(4) single retailer~~ ~~(5) single consumption event (e.g. party)~~ ~~(6) single product type or species~~ ~~(7) single growing area or harvest area~~ ~~B. Have any post harvest handling issues been identified that may have contributed to the occurrence of illness(es) including but not limited to harvesters, dealers, restaurants, retail, common carriers, or consumers.~~ ~~C. Production Consideration~~ ~~(1) Harvest event(s) and amount of production from growing area or areas (if commingling has occurred).~~ ~~(2) Number of harvesters associated with implicated shellfish~~ ~~(3) Number of dealers associated with implicated shellfish~~ ~~(4) Determine likelihood of product remaining in the marketplace (shellstock vs. in-shell vs. fresh shucked vs. frozen shucked).~~ ~~(5) Harvest or culture practices including wet storage, relay, resubmergence, transplant, etc.~~ ~~D. Strength of evidence, i.e. the evaluation should consider strength of evidence collected in relation to items .05 A., B., and C. above.~~ **.07 Guidance on Studies Used in the Reopening of an Area Temporarily Placed in the Closed Status Due to an Emergency Condition, a Discharge of Raw Sewage, or when Conditional Area Management Plan (CAMP) Performance Standards are not Met**
12. Public Health Significance	Recalls are an important tool used by dealers and Authorities to control the distribution of contaminated shellfish and minimize or eliminate the possibility of consumers becoming ill. The revised guidance submitted by the ISSC Recall Committee explains how to conduct a successful recall and provides job aids dealers and Authorities can use to train for or execute a recall.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A – Included in proposal text.