From Food Food Forum

Proposed

SHELLFISH RECALL POLICY

SUMMARY

The purpose of this proposed mandatory recall policy is to outline the procedures for states and the regulated industry participating in the National Shellfish Sanitation Program to follow when conducting recalls of shellfish products. The policy also defines the roles and responsibilities of the Food and Drug Administration in monitoring and reviewing shellfish recall actions.

This document is not worded in the usual and customary format of the National Shellfish Sanitation Program guidelines.

I. INTRODUCTION

This shellfish recall policy provides guidelines, directives, and responsibilities for conducting effective recalls of violative shellfish products and establishes procedures for firms to follow in order to achieve that goal. This policy also outlines monitoring and assessment strategies for state regulatory agencies participating in the National Shellfish Sanitation Program (NSSP) and the Food and Drug Administration (FDA) to utilize in determining the adequacy of a firm's recall efforts.

A. NSSP Background

The NSSP is a cooperative program administered by FDA, regulated and enforced by cooperating state agencies, and complied with by the shellfish industry. The NSSP is based on public health principles and controls formulated at the original shellfish sanitation conference convened in 1925 by the Surgeon General of the U.S. Public Health Service. It is designed to prevent human illnesses associated with the consumption of raw oysters, clams, mussels, and scallops (scallops are excluded when the final product is the shucked adductor muscle only). Sanitary controls cover all phases of the growing, harvesting, shucking, packing, and distribution of raw fresh and fresh-frozen shellfish. Shellfish products that are breaded, thermally processed, or hermetically sealed and fully cooked are not subject to the provisions of the NSSP.

The NSSP is governed by the Interstate Shellfish Sanitation Conference (ISSC), a voluntary tripartite organization comprised of state agencies, federal agencies (FDA, EPA and the Department of Commerce), and the shellfish industry. The goal of the ISSC is to promote molluscan shellfish sanitation and safety to ensure only safe and wholesome shellfish products intended for human consumption enters interstate commerce.

The ISSC has adopted the NSSP Manuals of Operation Parts I and II, which has now been changed to a Model Ordinance document. The NSSP sets forth the standards and procedures for governing shellfish sanitation, including growing area classification, laboratory procedures, patrol of closed areas, harvesting, processing, and shipping. The NSSP guidelines are intended to allow participating states to promulgate laws and regulations, providing them the legal basis for implementing adequate controls to ensure the safety and quality of molluscan shellfish.

B. FDA/ISSC Agreement

FDA established a Memorandum of Understanding (MOU) with the ISSC in 1984. This MOU delineates the responsibilities of FDA and the State Shellfish Control Authority (SSCA) of each participating state. In the MOU, FDA acknowledges state and local health and environmental authorities as having the primary role of enforcing laws to prevent and suppress illnesses and diseases caused by shellfish consumption. The MOU further acknowledges the ISSC as the principal organization of shellfish officials that provide guidance and counsel on matters relating to the sanitary control of shellfish. In addition, FDA establishes MOU's with sovereign nations that meet NSSP criteria and conducts periodic foreign program evaluations using the same criteria as that applied to states.

FDA is responsible for conducting evaluations of the shellfish sanitation program of participating state governments. Shellfish program evaluations are the mechanism FDA utilizes to determine the uniform adoption and implementation of criteria established in the NSSP. Program evaluations identify which program elements, or portions of program elements, do not fully meet the NSSP. FDA Regional Shellfish Specialists interact with state officials to audit state shellfish programs to ensure compliance with the NSSP. Their goal is to ensure that state officials comply with NSSP criteria for classifying shellfish growing waters and controlling illegal harvest activities in addition to reviewing state oversight of processing plant sanitary conditions, record keeping and product labeling. Regional Shellfish Specialists also provide training, consultation, research, and technical assistance in support of state and international shellfish program operations.

FDA and the ISSC strive to foster and improve shellfish safety and quality through mutually recognized responsibilities. The ISSC agrees to inform FDA of State programs not in substantial compliance with the NSSP, or when any interstate shipments of shellfish are not in compliance with the NSSP or may be in violation of the FD&C Act. The ISSC also reviews reports submitted by FDA concerning state program deficiencies, informs FDA of the recommendations made or actions taken to correct such deficiencies, and assists FDA with corrective measures. FDA agrees to inform the ISSC when any state shellfish sanitation control program is found to be not in substantial compliance with NSSP guidelines and criteria. The ISSC and FDA strive to jointly resolve problems concerning interpretation of the NSSP and resolve disagreements between States or between FDA and States concerning implementation of NSSP shellfish sanitation controls.

C. Product Recalls

Recalls are an effective method of protecting the public health and well being from products which present a risk of death, injury or are otherwise defective. Recall actions taken by firms are intended to protect the public health by removing affected product from commerce. Recalls are generally more efficient, more timely, and afford better consumer protection than formal administrative or civil actions, especially when the product has been widely distributed. Seizures or other court action may be indicated when a firm refuses to undertake a recall as requested by FDA or a state agency, where there is sufficient reason to believe a recall would not be effective, the recall is determined to be ineffective, or that a violation is continuing.

D. FDA Recall Authority

FDA responsibilities for preventing foodborne illness are fulfilled under the Public Health Service Act and the Food, Drug and Cosmetic Act (FD&C Act). The Agency's recall policy is provided in Title 21 of the Code of Federal Regulations (21 CFR), Parts 7.40 through 7.59. These sections set forth specific recall criteria FDA follows when monitoring recalls and assessing the adequacy of a firm's recall efforts. FDA requested recalls, normally reserved for urgent situations, are directed to

the firm that has primary responsibility for the processing, manufacture and marketing of the product to be recalled.

FDA District Directors have the overall responsibility of assuring the FDA audit program for all recalls is implemented. District Recall Coordinators and appropriate supervisory personnel are the principals normally responsible for FDA management of these recalls.

II. SHELLFISH RECALL PROCEDURES

The primary purpose of a shellfish recall is for certified shellfish dealers to remove from commerce all bivalve molluscan shellfish products which are in violation of NSSP guidelines, state regulations, or FDA laws. This includes shellfish products that have actually or are potentially contaminated with marine biotoxins, sewage, or any other poisonous or deleterious substances, or which are misbranded or otherwise improperly labeled.

FDA acknowledges in the ISSC MOU that state health and environmental authorities have the primary role of regulating certified shellfish firms operating under the NSSP. In accordance with this MOU, the appropriate SSCA is considered primarily responsible for monitoring shellfish recalls of certified firms operating under the NSSP. It is also the responsibility of the SSCA to inform FDA of the recalling firm's progress, provide FDA with status reports within the timeframes specified in Part II, Section B of this policy, and verify the satisfactory disposition of recalled products. FDA will not conduct or direct routine recalls for bivalve molluscan shellfish products where it determines the SSCA has managed the recall in accordance with this policy.

A. Industry Responsibility

A certified firm may decide to voluntarily initiate a recall of shellfish products or may be directed by the SSCA or FDA to conduct a recall. It is the responsibility of the recalling firm to conduct the actual recall. The recalling firm has an obligation to determine the distribution chain of the recalled product and immediately contact all known, affected consignees through any available means. It is also the responsibility of the recalling firm to provide to all identified consignees, in writing, pertinent information regarding the product being recalled, the reason for the recall, instructions to stop product distribution, and what to do with any returned product.

If a product is not hazardous, a recall may be directed only at wholesale purchasers. For more serious defects, the firm will conduct a recall to the retail level. Notifications should be brief and contain a concise statement of the reason for the recall. It must clearly identify the product by name, type, and/or lot numbers, specify the known or potential hazard, and provide instructions for consignees to follow in handling the recall. Instructions should direct accounts involved in further distribution of the recalled product to promptly initiate sub-recall efforts in a similar manner as indicated above. The written communiqué to sub-accounts should be in addition to any other means of notification.

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

1. Immediately notify the State Shellfish Control Authority (SSCA) in the certified dealer's state, unless directed initially by the SSCA, that a product recall has been initiated;

2. Immediately notify the receiving shipper or other receiver/user that a product recall has been initiated;

3. Provide the SSCA 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;

(d) the dates of harvest and shipment as they appears on the shipping tag or invoice;

4. 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 (if available) and date of reshipment.

(d) all product being held and considered embargoed;

5. Advise the receiver that:

(a) the product is not to be sold or shipped;

(b) unless advised otherwise by the SSCA, the product is to remain on the premises until the SSCA representative or other designee arrives;

(c) all receiving and shipping records and invoices for implicated products are to be available for inspection by SSCA officials.

The recalling firm has the initial responsibility for determining if the recall is progressing satisfactorily. It is also the obligation of all recalling firms 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.

B. State Responsibilities

States agencies participating in the NSSP, either as a shellfish producing or receiving state, are the primary authority for controlling and regulating shellfish processing activities. This may include evaluating and approving shellfish growing areas, monitoring and controlling harvest activities, and inspecting and certifying firms in the processing and distribution of raw fresh and fresh-frozen shellfish. Under the FDA/ISSC MOU, the SSCA is also responsible for regulating and directing recalls conducted by the certified shellfish firms within its jurisdiction.

Whenever an SSCA determines a recall is necessary, it will issue written notification to the FDA district office in which the recalling firm is located of the need for a product recall. The notification shall specify the nature of the violation, any recommended recall strategy, and any other information appropriate to the recall. The SSCA should also notify the Regional Shellfish Specialist assigned to that state of the recall.

Whenever FDA determines a product recall is necessary, it will issue written notification to the SSCA responsible for regulating the firm in question. This notification shall state the nature of the violation and the section of the FD&C Act or CFR that gives FDA the authority to initiate the recall. It should clearly describe the product, lots, serial numbers, etc. to be recalled and provide a time frame for the SSCA's reply.

The SSCA will provide a written recall progress update report to FDA within two (2) working days

of initiation of the recall. This report will include the following information.

1. The name and address of the recalling firm/processor:

   This includes the complete name and address of the recalling firm; the type of firm (i.e., processor, importer, broker, repacker, own label distributor); the complete name and address of the processor if different from the recalling firm; and identify any firms which processed or handled the product, or supplied components which might have been responsible for the problem. Also indicate which firm appears to be responsible for the violation.

2. The identity of the affected product:

   For each product, provide as applicable: the name and a brief description of the product; type or form; size or quantity; and description of the shipping or unit package.

3. The reason for the recall:

   Provide detailed information as to how the product is defective and violates the FD&C Act or other statutes.

4. Product identification code/lot numbers:

   List all lot and/or serial numbers, product numbers, packer or processor numbers, etc., which appear on the product or its labeling.

5. Complete distribution records of all shipments of the suspect lots:

   Include complete names and addresses for all domestic and foreign consignees.

6. Legible copies of all affected product labeling:

   For each product, provide: the brand name; name, address, and type of responsible firm on the label; and the number and description of private labels.

7. Pertinent quality control/analytical records:

   Include any analytical findings in qualitative and/or quantitative terms; indicate if it's the firm's or SSCA's analysis and which laboratory was involved.

The SSCA should offer guidance to the recalling firm and assist the firm in recall communications to consignees so that the product will be promptly removed or corrected. All retail and direct accounts should be instructed by the recalling firm to contact any sub-accounts which may have received the product. It may be necessary to extend the depth of the recall to the consumer level if the recall is of a serious or life-threatening nature.

The investigating SSCA is responsible for informing the monitoring FDA district and/or Regional Shellfish Specialist of the progress and status of the recall. The SSCA will verify the firm's receipt of the recall notification and make arrangements to visit/inspect the firm as soon as possible.

Coordination and assistance with the FDA District office in monitoring the recall may be necessary in special situations. If the SSCA encounters unreasonable delays by the recalling firm or fails to notify FDA of the status of the recall within specified time frames, the FDA District has the option of immediately initiating its own recall procedures.

The SSCA will review and copy or seize all receiving and shipping records and invoices pertinent to the affected product. The SSCA investigator should verbally apprise management that, when there is product to be returned for reconditioning or destruction, the SSCA office should be consulted prior to the initiation of such action. Management should also be advised that the SSCA representative or FDA must witness or otherwise verify product disposition. If the recall has been completed before FDA's knowledge of it, the SSCA must provide FDA with documentation of actions taken to dispose of or recondition the recalled products. This documentation may include processing records or laboratory analysis, signed destruction receipts, or corporate official's signed statement on firm's stationery.

Affected product or product which cannot be determined to be safe (due to inadequate identification, cross contamination or commingling) will be destroyed by denaturing and disposal based upon the nature of the contamination and consultation of SSCA and other officials. Product destruction, if necessary, will be witnessed by the SSCA or other designated representative. Records shall be made of product type, quantity, harvest area, harvest date and harvester/shipper of all product embargoed or destroyed.

SSCA officials normally have the primary responsibility for determining the effectiveness of the firm's recall strategy. The SSCA will prepare a complete recall summary after inspecting the firm and determining whether there have been reports of injuries, illness, or other complaints to either the company, FDA, or the state. The SSCA will forward the recall summary documents to the appropriate FDA Regional Shellfish Specialist and/or District Recall Coordinator within five (5) working days of the initiation of the recall. The recall summary will include:

1. The quantity of recalled product recovered or number of units corrected;

2. The disposition/status of returns and held stock (when, where, and how);

3. Number and type of product samples collected;

4. State laboratory worksheets, if applicable;

5. The recall awareness/initiation date;

6. Date the recall was completed;

7. Provide inspection results (e.g., GMP) or other evidence where appropriate;

8. List in chronological order any complaints or injuries associated with the product.

The recall summary will also address the results of the SSCA's investigation and, if not provided in the monitoring report, will include copies of the product labeling, the firm's relevant quality control records, and the firm's recall strategy.

In the event FDA determines the recalling state failed to:

$ notify FDA of a state or firm initiated shellfish recall;

$ initiate a recall requested by FDA;

$ provide the FDA with recall monitoring or recall summary reports within specified timeframes;

$ take appropriate regulatory actions against firms which fail to conduct a recall; or

$ administer an effective recall,

the FDA District Recall Coordinator, in cooperation with the Regional Shellfish Specialist, will document the state's actions. A determination by FDA that the SSCA has conducted an ineffective recall will result in that state being considered for referral to the ISSC as an unresolved issue. FDA may also institute recall actions in accordance with agency policy.

C. FDA Responsibilities

The FDA district office in which the recalling firm is located will be primarily responsible for obtaining recall information from the appropriate State and local officials and monitoring shellfish recalls. The District Recall Coordinator and Regional Shellfish Specialist(s) will communicate to confirm that each is aware of the recall situation. Although Regional Shellfish Specialists are the principle agency contacts to states participating in the NSSP, FDA District Recall Coordinators function as the main agency liaison during all recalls. The District Recall Coordinator, in conjunction with the Regional Shellfish Specialist if necessary, will be responsible for coordinating with the appropriate SSCA officials in arranging for any necessary assistance in conducting the recall. FDA may directly seek to assist the SSCA in the recall but will not ordinarily contact the recalling firm without SSCA concurrence.

The District Recall Coordinator will receive and review a copy of all pertinent recall documents to evaluate, on continuing basis, the overall effectiveness of recall activities. The District Recall

Coordinator will also prepare a recall notification in accordance with Regulatory Procedures Manual (RPM) Chapter 7 and immediately forward copies of any recall notification communiqués (letters, response cards, etc.) submitted by the SSCA to the FDA Center for Food Safety and Applied Nutrition (CFSAN). Within two (2) working days of receiving notification of a shellfish recall from the monitoring FDA District office, CFSAN will classify the recall in accordance with FDA policy and assign the recall a number.

As provided in RPM Chap. 7, when shellfish recalls involve distribution to foreign countries other than Canada, FDA will notify the International Affairs Staff (IAS) of all recalls considered equivalent to an FDA Class I recall. When specific foreign consignees are identified, FDA will forward the appropriate information to IAS, which responds to all recall related requests received by the agency from American embassies. If necessary, the FDA district office will advise IAS of imported product recalls in the effort to locate all importers of the violative product.

D. FDA Recall Review

It is the policy of FDA to closely monitor product recalls and assess the adequacy of a firm's recall efforts in order to verify that the recalled product is returned for reconditioning or destruction. Although FDA will defer oversight of shellfish recalls to state agencies, it must be assured of the successful completion of the recall. However, if the relevant FDA district office determines that:

$ the recall extends to the consumer-user level;

$ the confidential business records of a firm's customers are not accessible;

$ wholesalers, distributors, or retailers do not cooperate;

$ the public remains at risk because of the urgency of the situation;

$ the SSCA does not provide FDA with adequate recall information within specified timeframes;

$ the recall is determined to be ineffective; or

$ distributor states are unable to effect the necessary recall actions within two (2) days of the determination to recall,

the District Recall Coordinator and the Regional Shellfish Specialist will discuss the situation with the recalling SSCA and determine the appropriate FDA administrative or legal action recommended against the recalling firm.

The FDA district office will forward all pertinent information concerning inadequate trends, control weakness, or similar inadequacies to the appropriate FDA Center units and Regional Shellfish Specialists for consideration. In addition, the district office will prepare and promptly send a notification letter to the SSCA, with a copy to the recalling firm, stating the agency's position with respect to the recall. The letter should also state the recall will be published in the FDA Enforcement Report. The letter should encourage proper corrective action, and request periodic status reports from the SSCA in accordance with this shellfish recall policy. A statement will be included that failure to conduct an effective recall could result in FDA initiating recall actions in accordance with agency policy, seizure of the violative product or other legal sanctions under the FD&C Act or related statutes, and referral of the SSCA to the ISSC as an Unresolved Issue.

The successful completion of any recall does not preclude FDA from taking further regulatory action against a responsible firm, but such action will be a factor taken into consideration by the agency when reaching a final decision.

E. Recall Publication

FDA will not ordinarily issue notices or warnings to the general public and/or health professionals, trade associations, etc., for effective shellfish recalls. FDA will include classified recalls in the agency's weekly Enforcement Report, regardless of age or status, in accordance with agency policy. For shellfish recalls which pose a serious health hazard, where intense publicity is anticipated, when the recall is extended to the retail or consumer level, and/or where their assistance is requested, the FDA District Recall Coordinator may inform state and local officials outside of the recalling state. The FDA District Recall Coordinator will also notify the Division of Federal-State Relations of such recalls.

F. Publicizing Health Alerts

Shellfish recalls which are not FDA-initiated, do not exceed agency Action Levels or Tolerance Levels, or are not in violation of FDA law will not normally be publicized in any manner without the concurrence of the SSCA. However, in the event FDA determines the public health is seriously jeopardized, preliminary communication designed to reach the individual consumer may be required to prevent unnecessary injury. In such instances, FDA will prepare press releases for public health alerts or warnings in cooperation and coordination with the SSCA and the FDA Press Relations office.

Proposed
FDA Bivalve Molluscan Shellfish Recall Policy

The purpose of this proposed Food and Drug Administration (FDA) Recall Policy is to define and establish agency procedures for monitoring interstate bivalve molluscan shellfish recalls which are initiated by states or regulated firms participating in the National Shellfish Sanitation Program (NSSP).

Proposed Policy

It is proposed that the following language be added to the appropriate sections of the FDA Regulatory Procedures Manual (RPM), Chapter 7 and the Investigations Operations Manual (IOM), Chapter 8:

RPM Chapter 7, Recall Procedure
Interstate Bivalve Molluscan Shellfish Shipments

The FDA will not ordinarily be involved in classification and auditing of Interstate Bivalve Molluscan Shellfish Shippers product recalls where such actions have been, or are being, handled expeditiously and appropriately by the state(s). However, the FDA district office in which the recalling firm is located must be assured that all states involved in an Interstate Bivalve Molluscan Shellfish Shippers plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, states issue warning to protect the pubic health. However, in the event that FDA determines that the states are unable to effect the recall actions necessary, the Agency will classify, publish, and audit the recall, including issuance of a public warning when indicated."

IOM Chapter 8, Recall Activities
811.2 Interstate Bivalve Molluscan Shellfish Shippers

The FDA will not ordinarily be involved in the processing, classifying or monitoring Interstate Bivalve Molluscan Shellfish Shippers product recalls where such actions can be handled in a timely manner by the appropriate state(s). However, FDA must be assured all states involved in an Interstate Bivalve Molluscan Shellfish Shippers plant's recall are participating in ensuring removal of the product from commerce and that appropriate public warning has issued to protect the pubic health.

Policy Justification:

In 1982, State Shellfish Control officials and the FDA selected the National Conference of Interstate Milk Shippers (IMS) as the foundation for developing a shellfish organization. This resulted in the formation of the Interstate Shellfish Sanitation

Conference (ISSC), a voluntary tripartite organization comprised of the shellfish industry, participating state agencies, and federal agencies. Based on the intent of following the IMS voluntary public health program for developing Shellfish Program procedures, this proposed Bivalve Molluscan Shellfish Recall Policy is modeled on the IMS Recall Policy.

This Proposed Interstate Bivalve Molluscan Shellfish Recall Policy is consistent with ISSC Policy and satisfactory compliance criteria of the Model Ordinance (MO) of the ISSC. M.O. Chapter I@.02.H(2)(b)(iii) requires state shellfish control authorities have enforcement authority sufficient to initiate a recall of any distributed shellfish which constitutes a major public health threat. Additionally, in response to illness outbreaks associated with bivalve molluscan shellfish, M.O. Chapter II@.01.C(4) requires state shellfish control authorities to promptly recall any shellfish products that have been distributed through interstate commerce and originated from an implicated shellfish growing area.

This Proposed Interstate Bivalve Molluscan Shellfish Recall Policy is also consistent with the Molluscan Shellfish Compliance Program CP7318.004 and the "Memorandum of Understanding between the ISSC and the FDA."

> **CP7318.004. The Molluscan Shellfish Compliance Program, 1999 (draft)**
> Section III.5 Illness Outbreaks
>
> "Specialists shall give top priority and devote their full attention to shellfish borne illness outbreaks as soon as they are reported. In the event of illness outbreaks, Specialists shall inform the Office of Seafood and Division of Cooperative Programs as new information becomes available. Specialists shall be responsible for monitoring state and FDA actions to ensure that growing area closures and product recalls are consistent with the requirements of the NSSP Model Ordinance. FDA and other federal assistance to affected states should be coordinated by the Regional Specialist."

If adopted, all participating parties are expected to comply with the requirements and provisions of this shellfish recall policy.

BIVALVE MOLLUSCAN SHELLFISH RECALL PROCEDURES

Recalls are an effective method of protecting the public health and well-being from products which present a risk of death, injury or are otherwise defective. Recall actions taken by firms are intended to protect the public health by removing affected product from commerce. Recalls are generally more efficient, more timely, and afford better consumer protection than formal administrative or civil actions, especially when the product has been widely distributed. Seizures or other court action may be indicated when a firm refuses to undertake a recall, where there is sufficient reason to believe a recall would not be effective, the recall is determined to be ineffective, or that a violation is continuing.

The primary purpose of a shellfish recall is for certified shellfish dealers to remove from commerce all bivalve molluscan shellfish products which are in violation of National Shellfish Sanitation Program (NSSP) guidelines, state regulations, or Food and Drug Administration (FDA) laws. This includes shellfish products that have actually or are potentially contaminated with marine biotoxins, sewage, or any other poisonous or deleterious substances, or which are misbranded or otherwise improperly labeled.

The objective of this document is to define the satisfactory compliance procedures for conducting bivalve molluscan shellfish product recall within the scope of the NSSP. This proposal addresses the roles and responsibilities for participating State Control Authorities (SCA) and the regulated industry to follow when engaged in shellfish product recalls. It also outlines FDA activities for monitoring and reviewing state shellfish program recall actions.

The intent of this document is that be introduced as an issue at the next annual Interstate Shellfish Sanitation Conference (ISSC) as the basis for establishing NSSP recall guidelines. The issue will be submitted to the FDA Office of Seafood for review and editing in an acceptable NSSP Model Ordinance format prior to its presentation to the ISSC.

A. Industry Responsibility

"When a certified dealer conducts a recall of shellfish products, the firm shall:

1. Immediately notify the SCA in the certified dealer's state, unless directed initially by that SCA, that a product recall has been initiated.
2. Immediately notify the receiving dealers and other known consignees that a product recall has been initiated.
3. Provide the SCA and the receiver of the product with:
   (a) The type and quantity of shellfish being recalled;
   (b) The name and, as necessary, the license number of each harvester or certification number of each dealer;
   (c) The name of the harvest area;
   (d) The date of harvest as it appears on the shipping tag or invoice; and
   (e) The date of shipment as it appears on the invoice or bill of lading.

4. Direct each receiver of the recalled product to examine their receiving records and invoices and provide:
   (a) The quantity of product received;
   (b) The quantity remaining;
   (c) If applicable, the quantity shipped and to whom; including name, address, phone number, and date of reshipment; and
   (d) The status of all products known to be held and considered embargoed.
5. Advise the receiver that:
   (a) The product is not to be sold or shipped or redistributed;
   (b) Customers who received the product shall in turn notify its customers that may have received the product of the product recall, and to follow recall procedures;
   (c) Unless directed otherwise by the SCA, the product is to remain on the premises until the SCA representative or other designee arrives to witness product destruction; and
   (d) All receiving and shipping records and invoices for implicated products are to be available for inspection by SCA officials."

Public Health Explanation

A certified firm may decide to voluntarily initiate a recall of shellfish products or may be directed by the state regulatory authority or FDA to conduct a recall. It is the responsibility of the recalling firm to conduct the actual recall. The recalling firm has an obligation to determine the distribution chain of the recalled product and immediately contact all known, affected consignees through any available means. It is also the responsibility of the recalling firm to provide in writing to all identified consignees any pertinent information regarding the product being recalled, the reason for the recall, instructions to stop product distribution, and what to do with any remaining product.

The recalling firm has the initial responsibility for determining if the recall is progressing satisfactorily. It is also the obligation of all recalling firms 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.

B. State Responsibilities

"When a certified dealer conducts a recall of shellfish products, the SCA shall:

1. Provide a recall progress update report to the FDA Regional Shellfish Specialists within two (2) working days of initiation of the recall. The recall monitoring report, which may be verbal or written notification, will include the following information:
   (a) The name and address of the recalling firm/processor, plus certification numbers;
   (b) The identify of the affected product;
   (c) The reason for the recall;
   (d) Product identification (harvest date, harvest location, quantity);
   (e) Complete distribution and redistribution of all shipments of the suspect lots; and
   (f) Final disposition of all recalled product.

2. Prepare a complete recall summary that determines the effectiveness of the recall. The SCA will forward the recall summary documents to the appropriate FDA Regional Shellfish Specialist within five (5) working days of the initiation 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;
(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) Plant inspection results (e.g., GMP) or other evidence where appropriate; and
(g) A listing, in chronological order, of any complaints or injuries associated with the product."

Public Health Significance

The FDA and ISSC mutually agree in the FDA-ISSC Memorandum of Understanding (MOU) that the ISSC procedures contain the principal standards and guidelines for the sanitary control of shellfish. State shellfish regulatory officials, either in a shellfish producing or receiving state, are further acknowledged in the MOU as the primary authority responsible for controlling and regulating shellfish processing activities under the NSSP. Consistent with this acknowledgement, the appropriate SCA is responsible for regulating and directing recalls conducted by certified shellfish firms within its jurisdiction.

The SCA is responsible for contacting its certified firms and monitoring shellfish recall activities. SCA officials also have the responsibility for determining the effectiveness of the firm's recall strategy and actions. When a recall is initiated, the SCA is expected to inform the FDA Regional Shellfish Specialist assigned to that state of the recall. The SCA will also notify the SCA of the receiving state(s) and the ISSC. Such notification will specify the nature of the violation, the recommended recall strategy, and any other information appropriate to the recall. It is also the responsibility of the SCA to inform FDA of the recalling firm's progress, provide FDA with status reports within the timeframes specified in Section B of this policy issue, and verify the satisfactory disposition of recalled products. The recall summary submitted to FDA will also address the results of the SCA's investigation of the recall and, if not provided in the monitoring report, the firm's relevant quality control records and recall strategy.

C. FDA Responsibilities

"When a certified dealer conducts a recall of shellfish products, the FDA shall ensure that:

1. Regional Shellfish Specialists monitor SCA and, if necessary, FDA actions to ensure that the product recall is consistent with the requirements of the NSSP Model Ordinance.
2. Regional Shellfish Specialists inform the Office of Seafood and Division of Cooperative Programs as new or pertinent recall information from the SCA becomes available.
3. Regional Shellfish Specialists coordinate all FDA and other federal assistance provided, as necessary, to affected states.

4. If the Regional Shellfish Specialists determine that the states are unable or unwilling to effect the necessary recall actions, the Agency will classify, publish, and audit the recall, including issuance of a public warning when indicated.
5. It does not classify or conduct recall effectiveness checks of recalled bivalve molluscan shellfish products, or issue public warning without the concurrence of the appropriate SCA, where such actions are identified as being, or having been, handled expeditiously and effectively by the SCA."

Public Health Significance

FDA acknowledges in the FDA-ISSC MOU that the appropriate SCA is considered primarily responsible for contacting and monitoring shellfish recalls for certified firms operating under the NSSP. It will be the responsibility of the SCA to inform FDA of the recalling firm's progress, provide FDA with status reports within the timeframes specified in Section B of this policy issue, and verify the satisfactory disposition of recalled products. FDA will not ordinarily conduct or direct routine recalls or issue press releases for bivalve molluscan shellfish products where it has determined the SCA has managed the recall in accordance with this policy issue.