



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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December 23, 2011

Mr. Steven G. Bowman, Commissioner  
Virginia Marine Resources Commission  
2600 Washington Avenue  
3<sup>rd</sup> Floor  
Newport News, VA 23607

RECEIVED  
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MARINE RESOURCES  
COMMISSION

Dear Commissioner Bowman:

I am writing this letter to provide you with the findings of the Food and Drug Administration (FDA) Annual State Shellfish Program Evaluation. Enclosed is our 2011 Shellfish Program Evaluation for the State of Virginia as required by the National Shellfish Sanitation Program (NSSP). The Virginia Marine Resources Commission (VMRC) are responsible for the Shellfish Control of Harvest (Patrol) programs under the NSSP. The Shellfish Processing, Shipping and Plant Certification and Growing Areas Classification program activities are the responsibility of The Virginia Department of Health (VDH), Division of Shellfish Sanitation (DSS) and a similar letter has been sent to VDH Commissioner Dr. Remley.

I am pleased to report that the Virginia Shellfish Program was found to be operating in conformance with the NSSP requirements by a dedicated staff of professionals that have high level of experience and expertise in their field of public health relating to shellfish sanitation and safety. The VMRC staff is effectively implementing and enforcing the shellfish program standards and the associated requirements for the program elements under their jurisdiction.

The VMRC was found to be providing the necessary patrol of shellfish growing/harvest waters to prevent the illegal harvest of shellfish within the State of Virginia. In addition the agency was found to be maintaining adequate oversight of the shellfish harvesters including the implementation of a risk reduction plan for the prevention of *Vibrio parahaemolyticus* (*Vp*) illnesses from the consumption of raw oysters harvested in Virginia. The FDA would like to take this opportunity to commend your agency and staff for developing and implementing a program of icing for rapid temperature reduction oysters during the warm weather months on-board harvest vessels during the harvest day. This was put into place by working together with the other regulatory agencies such as VDH and industry in order to reduce the risk of *Vp* from consumption of raw oysters. Also under this *Vp* risk reduction plan you monitor harvest boats that are outside the harvest curfew through a GPS tracking system. We know this took a great deal of time, effective communications, and oversight. FDA's Regional Shellfish Specialist, Gary Wolf was able to see the fruits of your labor while observing this process during the summer and reports that it was successful at chilling the oysters to safer temperatures on-board the harvest boats prior to off-loading.

I would like to thank you, Lt. Col. Warner Rhodes and his staff who have been very attentive to NSSP requirements and requiring harvesters to maintain compliance with NSSP regarding the *Vp* Control Plan. It was very obvious that the MRC/MRP and DSS were working very cooperatively with each other

to make this Program a success. I want to express our sincere appreciation to Marine Police Officers Captain Jamie Green and Officer Mike Morris for arranging for Mr. Wolf to accompany them on patrol activities in shellfish growing waters during the FDA evaluation.

I look forward to a continuing team effort between the DNREC and the FDA. Please feel free to contact me or Larry Stringer, Director, Cooperative Programs if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Melinda K. Plaisier', with a long horizontal flourish extending to the right.

Melinda K. Plaisier  
Regional Food and Drug Director  
Central Region

cc: HFS-325 (Burditt)  
HFS-325 (Ellwanger)  
HFR-CE2 (Stringer)  
HFR-CE450 (Jaworski)



**UNITED STATES FOOD AND DRUG ADMINISTRATION  
U.S. PUBLIC HEALTH SERVICE  
CENTRAL REGION**

**FY 2011  
ANNUAL PROGRAM EVALUATION REPORT  
OF THE COMMONWEALTH OF VIRGINIA SHELLFISH  
PROGRAM**

**ADMINISTERED BY**

**THE VIRGINIA MARINE RESOURCES COMMISSION**

**AND**

**THE VIRGINIA DEPARTMENT OF HEALTH  
OFFICE OF ENVIRONMENTAL HEALTH PROGRAMS  
DIVISION OF SHELLFISH SANITATION**

**Evaluator:  
Gary Wolf  
Shellfish Specialist**

**FDA ANNUAL PROGRAM EVALUATION REPORT**  
**Commonwealth of Virginia**  
**FY 2011**

The National Shellfish Sanitation Program (NSSP) is a Federal-State Cooperative Program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The Commonwealth of Virginia participates in the NSSP/ISSC as a shellfish producing, receiving, and shipping state. Virginia has four program elements that must conform to the minimum requirements set forth in the National Shellfish Sanitation Program (NSSP) *Guide for the Control of Molluscan Shellfish* in order for its dealers to ship to other participating states. This report summarizes FDA's Annual Program Evaluations of the NSSP elements for FY 2011 (October 2010 through September 2011). The evaluation assessed the overall effectiveness of the program as measured by the criteria set forth under the NSSP. Detailed Program Element Evaluation Reports (PEERs) for each evaluated element have been submitted to and reviewed by the division or agency responsible for administering that part of the program. The following is a summary of the findings of those reports for each NSSP element in FY 2011.

**A. Overall Program Status**

**1. Growing Area Classification Element**

**Status:** The Virginia Department of Health, Office of Environmental Health Services, Division of Shellfish Sanitation (DSS) administers the Growing Area Classification Element in the Commonwealth of Virginia. No follow up was required on this element from the FY 2010 Program Element Evaluation.

Thirteen growing areas were randomly selected for the FY 2010 FDA evaluation. A comprehensive review of the Sanitary Survey, Triennial Reevaluation, and Annual Update Reports was conducted. Field visits to these growing areas were conducted to verify sanitary survey report classifications, sample station locations, and identified pollution sources. Virginia performs a very thorough review of growing areas when classifying or annually re-evaluating them. No program-wide deficiencies were cited.

The program is well managed by knowledgeable, experienced staff. The Division's classifications of shellfish growing areas are supported by appropriate field work, reviews, and applications of NSSP standards. This element was found to meet the requirements of the *NSSP Guide for the Control of Molluscan Shellfish*.

## **2. Processing and Shipping Element and Standardization**

**Status:** DSS administers the shellfish Processing and Shipping Element and Plant Certification for the Commonwealth of Virginia. This element was evaluated by FDA Regional Shellfish Specialist (RSS) Charlotte Wilkins in FY 2011 to determine compliance with the NSSP. According to the FY 2010 FDA Compliance Program, 7318.004, this element is to be evaluated every two years unless there were NSSP non-conformance deficiencies. The evaluation consisted of the inspections of 13 processing plants and a file review. The FDA was accompanied by Ms. Julie Ray, State Standardization Officer (SSO) for Virginia DSS for most of the inspections and standardized Inspectors for the remainder. The inspections were conducted in November and December of 2010. Since a complete evaluation was conducted in FY 2009, an evaluation was not performed in FY 2010. No follow up was required on this element from the FY 2009 Program Element Evaluation

The FY 2011 evaluation was conducted by FDA RSS Wilkins and consisted of the inspections of fourteen processing plants and a file review. Virginia had 186 shellfish processing plants certified in the December 2010 Interstate Certified Shellfish Shipper's List (ICSSL), including 52 Shucker/Packers (SP), 2 Repackers (RP), 113 Shellstock Shippers (SS), and 19 Reshippers (RS). The visit to the Division's headquarters in Richmond VA on December 16, 2010 concentrated on the state's certification/re-certification program and file review to determine inspection frequency and follow up to inspectional findings. The certification for all Virginia shellfish dealers expire on September 30 each year. Using the November, 2010 Interstate Certified Shellfish Shippers List (ICSSL), 14 firms were randomly selected from the Virginia Certified Dealers listed.

There were no program-wide deficiencies cited during the FY 2011 evaluation based on review of the central files and discussion with staff and management. This element met the requirements of the NSSP MO for the FY 2011 Plant Evaluation. The status of the state's shellfish regulations and their equivalency to the NSSP MO will be addressed in FY 2012 by the FDA. In addition there were some Shellfish Plant Quality Control areas of concern observed. These concerns were described in detail in the FY 2011 FDA Processing and Shipping PEER.

In all of the files reviewed and during field evaluation, no firm was allowed to operate with any critical violations not immediately corrected, and if product was affected it was immediately embargoed and removed from the marketplace. If a dealer has failed to correct key or other deficiencies in the time frame specified on the inspection sheet, then the dealer would receive written notice. A re-inspection is done and if not corrected then the dealer is called into the DSS Richmond office for a conference and usually an agreement is made with specific time frames for correction. Written proceedings with the agreement are mailed to the dealer. If re-inspections find the firm failed to correct the deficiencies within the time frame then the firm's certification can be revoked. Critical deficiencies must be corrected immediately when found or the state requires the firm to cease operations until the deficiency is corrected; any product affected by the critical

deficiency is evaluated and appropriate action taken. File review found compliance schedules developed for violations cited.

Regarding Vp Control Plan for Virginia, a comprehensive Evaluation Report as requested by FDA's Center for Food Safety and Applied Nutrition (CFSAN) was conducted for Virginia and was provided to the New Jersey Department of Health and Senior Services and to the ISSC via CFSAN under separate cover in September 2011. The state's Vp Control Program including implementation was found to be substantial compliance with some recommendations for improvement provided.

**FDA Recommendations:** FDA recommends that DSS continue the many efforts and activities to encourage continued and stronger compliance by VA shellfish processing plants with NSSP MO requirements through constant training of the Certified State Shellfish Specialists and the industry.

**Standardization:** During FY 2011 FDA RSS Wolf provided Re-Standardization for DSS State Standardization Officer (SSO) Julie Henderson. This will now be in effect and current until 2016.

### **3. Control of Harvest (Patrol) Element**

**Status:** The Control of Harvest Element is administered by the Virginia Marine Resources Commission's (VMRC) Law Enforcement Division. The Virginia Marine Police have the responsibility for patrolling molluscan shellfish harvest areas in Virginia waters to assure illegal harvesting of shellfish does not occur. No follow up was required on this element from the FY 2010 Program Element Evaluation as the Evaluation indicated that the Agency meets or exceeds the criteria required for Patrol in the NSSP.

The FY 2012 FDA evaluation will focus on all aspects of Control of Harvest required under the NSSP including the updating of the Patrol Policy Document, Frequency of Patrol, Equipment and Enforcement.

**Enforcement Actions:** From July 1, 2009 to October 31, 2010, there were 16,328 hours spent conducting 94,842 inspections on polluted shellfish growing areas. There were eight summonses issued and eight convictions. Fines totaled \$1,710.00. On other shellfish enforcement there were 3,591 hours spent conducting 14,458 inspections on general shellfish enforcement. Summonses were issued on 76 violations with 57 convictions resulting in \$7,281.00 in fines.

**Harvester Education:** Harvesters in Virginia are annually sent or given harvester education material by the VDOH/ DSS per the NSSP requirement and in accordance with an MOU between the Department of Health and VMRC. The MOU states that the VMRC and the VDOH shall jointly observe and enforce sanitary construction and maintenance of shellfish

harvest and buy boats. Virginia specifically requires, under 4 VAC 20-1100-10 ET SEQ “Pertaining To Shellfish Handling”, harvesters to have a marine sanitation device on all shellfish harvesting vessels.

**Regulations:** Virginia Adopted regulations effective in FY 2011 in conjunction with Warm Water Harvest regulations for identifying shellfish with approved tags affixed to each container. This chapter amends and re-adopts, as amended, previous Chapter 4 VAC 20-1230-10 et seq. The effective date of the regulation is January 1, 2011 and now incorporates requirements for harvesters to tag all of their shellfish prior to shipping to a Virginia Certified Shellfish firms. As set forth in §28.2-903 of the Code of Virginia, “any person violating any provision of this chapter shall be guilty of a Class 3 misdemeanor, and a second or subsequent violation of any provision of this chapter committed by the same person within 12 months of a prior violation is a Class 1 misdemeanor.” In addition 4VAC 20-720-60 sets day and time limits for oyster harvesting. 4 VAC 20-610-60 requires mandatory reporting of oyster harvest and transactions by the licensed harvesters. 4 VAC 20-610-70 describes penalties for not registering and not reporting harvest and sales as being guilty of a Class 3 misdemeanor, and a second or subsequent violation of any provision of this regulation committed by the same person within twelve months of a prior violation is a Class 1 misdemeanor. Additionally, any person violating this regulation is subject to license suspension or revocation.

Legal penalties are sufficient to deter illegal harvest; most violations are a Class 1 misdemeanor with fines up to \$2,500 and up to 12 months in jail.

#### **4. Laboratory Element**

**Status:** The Virginia Shellfish Sanitation Program Laboratory Element is administered by DSS and it was not evaluated in FY 2010. The Laboratories’ operations and performance were last evaluated in 2007 for compliance with requirements established in the *NSSP Guide for the Control of Molluscan Shellfish*. Virginia depends on the services of three laboratories to meet its Shellfish Program needs. These Laboratories are located in White Stone, Norfolk and Accomac, Virginia. Each Laboratory demonstrated the ability to meet NSSP requirements earning them the laboratory status of conforming and enabling each facility to continue to provide analytical support to the Virginia Shellfish Sanitation Program. DSS reports no changes in laboratory operations since the 2007 evaluation.

### **B. Status of Deficiencies (If Any) Identified during Evaluation**

#### **1. Growing Area Classification Element**

**Present status:** In FY 2011 a Risk Category for Growing Area Evaluation frequency was conducted by FDA RSS Wilkins as per the FDA Molluscan Shellfish Compliance Program guidance document 7318.004 and found that the Commonwealth of Virginia did not require a comprehensive FDA evaluation for this element as they were in compliance with NSSP were currently in a medium risk category for production. FDA RSS Robert Connell will re-evaluative this status based on increased production and harvest and other activities from shellfish during FY 2012. In addition FDA will conduct a comprehensive Growing Area Classification evaluation in FY 2012.

Per CP 7318.004 Virginia's Risk is as follows:

Three risk factors have been identified for **Shellfish Growing Area Classification**. They are:

- (1) Production
- (2) Classification Complexity
- (3) Illness Outbreaks

(1) Production: Amended 01/16/2009: Assign the following point value based upon the average of the last three years harvest (in pounds) of the following shell stock as appropriate for the state; oysters (all species totaled), clams (all species totaled), mussels (all species totaled), and scallops (all species totaled) when the final product is whole or roe-on. Production will only be based upon shellfish harvested within state classified waters.

High Risk Factor (4) = > 4,700,000 pounds  
Medium High Risk Factor (3) = > 2,000,000 - 4,700,000 pounds  
Medium Low Risk Factor (2) = > 1,000,000 – 2,000,000 pounds  
Low Risk Factor (1) = < 1 million pounds

(2) Classification Complexity: Assign the following point value based upon the growing area classification complexity within the state:

High Risk Factor (4) = Approved, Restricted, Prohibited, and > 20% of the state's total number of growing areas have a Conditionally Approved or Conditionally Restricted classification.

Medium High Risk Factor (3) = Approved, Restricted, Prohibited, and < 20% of the state's total number of growing areas have a Conditionally Approved or Conditionally Restricted classification. (Seasonal such as closings for boating activity are conditional)

Medium Low Risk Factor (2) = Approved, Restricted, and Prohibited only

Low Risk Factor (1) = Approved and Prohibited only

(3) Illness Outbreaks (excluding Vp illness outbreaks):

Assign the following point value based upon the occurrence of illness outbreaks associated with shellfish from a growing area in the state being assessed.

High Risk Factor (3) = 2 or more outbreaks in past 5 years.

Medium Risk Factor (2) = 1 outbreak in past 5 years

Low Risk Factor (0) = No outbreaks in past 5 years

Based on the above calculations, Virginia currently is  $3 + 3 = 6$  or low risk range, however production may be up this year as aquaculture has dramatically increased in the state. There are numerous hatcheries, nurseries, and dealers growing oysters and clams.

Growing Area Classification Elements that do not meet overall NSSP requirements will be placed in the high risk category and will be evaluated annually until the state has demonstrated that the element is again in full compliance with the NSSP. Once the element is again in full compliance with the NSSP, the frequency of evaluation will be based on the element's risk category (high or low). Virginia was found in overall compliance with NSSP requirements. Thus, Virginia's growing areas do not have to be evaluated in FY 2011.

**Follow-up:** No corrective Action Plan was required, and no FDA follow-up is required.

Comprehensive information regarding the Growing Area Classification Element evaluation can be found in the FY 2010 FDA Growing Area Classification PEER.

## **2. Processing and Shipping Element and Standardization**

**Present status:** The FY 2011 evaluation conducted by FDA RSS Wilkins consisted of the inspections of fourteen processing plants and a file review. The FDA was accompanied by Ms. Julie Ray, SSO for Virginia DSS, for most of the inspections and standardized Inspectors for the remainder. The inspections were conducted in November and December of 2010.

Virginia had 186 shellfish processing plants certified in the December 2010 Interstate Certified Shellfish Shipper's List (ICSSL), including 52 Shucker/Packers (SP), 2 Repackers (RP), 113 Shellstock Shippers (SS), and 19 Reshippers (RS). The visit to the Division's headquarters in Richmond VA on December 16, 2010 concentrated on the state's certification/re-certification program and file review to determine inspection frequency and follow up to inspectional findings. The certification for all Virginia shellfish dealers expires on September 30 of each year. Using the November, 2010 Interstate Certified Shellfish Shippers List (ICSSL), fourteen firms were randomly selected from the Virginia Certified Dealers listed.

The Plant Sanitation Element of the Virginia Shellfish Sanitation Program is in compliance with the administrative requirements of the NSSP Model Ordinance (MO). Sanitation had greatly improved at all plants since the last evaluation as has compliance with HACCP. Stronger, more constant compliance with NSSP MO requirements by processing plants is needed as evidenced by observations made during the joint DSS/FDA inspections. Corrections have been accomplished at all of the facilities

inspected and attention to the noted deficiencies has been given to all Virginia's Shellfish dealers. FDA will continue to work with DSS to examine ways to obtain plant compliance with NSSP requirements.

**Note:** Additional information regarding the Processing and Shipping Element may be found in the FY 2011 FDA Processing and Shipping PEER and in the FY 2011 FDA *Vibrio parahaemolyticus* Control Plan Element Report.

### **3. Control of Harvest Element**

**Present status:** During August 3-5 and August 15-18, 2011 FDA RSS Wolf observed the Patrol agency for Virginia which is under the VMRC. This was part of an evaluation of the Virginia Vibrio Control Plan and its implementation for oyster harvest, transportation, time/temperature control and Certified Shellfish plant processing controls including pre-chilling prior to interstate shipment. A portion of the *Virbio parahaemolyticus* (Vp) Control Plan (CP) evaluation included the activities of VMRC in implementing the state's "Warm Weather Harvest" requirements for icing of oysters harvested in the James River and use of a GPS tracking device for those harvesting oysters in Virginia waters past the curfew time limit. FDA found the VMRC Officers to be properly equipped and trained in these requirements and the Virginia VpCP to provide the necessary oversight of harvest and landing of the oysters under this program. This evaluation (FDA *Vibrio* Control Plan Evaluation) was provided as a separate FDA PEER to the State of Virginia Program management and to the ISSC via FDA in September 2011. The FDA RSS conducted site audits by patrol vessel to observe oyster harvest patrols and to observe the enforcement of curfew, icing of oysters on-board vessels. Landing at docks and down-loading of the GPS tracking device from harvesters operating after the curfew hours was also observed.

Virginia Marine Police Officers are dedicated individuals who work diligently to enforce requirements of the NSSP. Administrative policies and procedures along with Virginia's laws regulating harvest were reviewed during this evaluation period. The FY12 FDA evaluation will focus on all aspects of Control of Harvest required under the NSSP including the updating of the Patrol Policy Document, Frequency of Patrol, Equipment and Enforcement.

**Note:** Additional information regarding the Control of Harvest Element can be found in the FY 2011 FDA Control of Harvest PEER.

#### **4. Laboratory Element**

**Present status: The DSS Laboratories were not evaluated during FY 2011. The three DSS Laboratories were found to be in the “Conforming Status” in FY 2007.** Additional information regarding the Laboratory Element evaluation can be found in the FY 2007 FDA Laboratory Evaluation Report.

#### **C. Information on Illnesses Cases/Outbreaks and/or Recalls**

There were no outbreaks during FY 2011 associated with consumption of shellfish harvested from Virginia waters and no illness cases associated with any outbreaks from oysters harvested from other states. There have been no confirmed illness outbreaks of *Vibrio parahaemolyticus* (Vp) from the consumption of oysters harvested in Virginia waters within the past five years. This includes the current reporting period through the time this Report was composed in August 2011.

Regarding *Vibrio vulnificus* (Vv) there has been only one Vv case etiologically confirmed shellfish-borne case since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of Virginia (confirmed by ISSC at the October 2011 meeting). Therefore the Authority does not need a Vv Control Plan (CP) at this time.

#### **D. Vp Control Plan (Vp CP) Implementation and Enforcement FY 2011**

The FDA found that Virginia is effectively implementing and monitoring the Vp CP as per the Model Ordinance and based on Virginia “Warm Water Shellfish Requirements” to reduce the risk of Vp illnesses.

During August 3-5 and August 15-18, 2011 FDA RSS Wolf conducted field evaluations and observed the activities of the Patrol agency for Virginia which is under the VMRC as well as the shellfish Plant Processing & Shipping inspection agency which is under the VDH/DSS. This was conducted as part of the FY 2011 evaluation of the Virginia Vp CP and its implementation for oyster harvest, transportation, time/temperature control and certified shellfish plant processing controls including pre-chilling prior to interstate shipment. As part of the evaluation FDA observed the activities of VMRC in implementing the state’s “Warm Weather Harvest” requirements for icing of oysters harvested in the James River and use of a GPS tracking device for those harvesting oysters in Virginia waters past the curfew time limit. Also Certified Shellfish firms were visited to audit the pre-chilling of the oysters to 50 degrees F prior to shipment and well as other requirements under the NSSP MO. FDA RSS Wolf observed the following:

1. Oyster harvest, the time of harvest and vessel landing;

2. Oyster off-loading and the temperature of oysters at the off-loading step; and
3. Loading oysters onto the refrigerated trucks of the Certified Dealers purchasing the oysters in order to assess the compliance with the NSSP MO and the Virginia Regulations for their 2011 Vp CP.

This included three dealer trucks, six plants and several observed patrols. In addition, 14 vessels were observed and boarded. In all cases the oysters in the bin had layers of ice in-between the oysters. Four firms were also evaluated.

#### Observations:

- Post Harvest Processing- there are two Certified Dealers in Virginia that have received prior State approved / FDA reviewed Post Harvest Processing (PHP) Validations for oysters relating to Vibrio reduction, however neither firm is currently utilizing this on the label. These Firms were not inspected for PHP during this Evaluation for the reason mentioned above.
- The VDH/DSS staff had inspected their Certified Shellfish Plants prior to the start of the 2011 Vp CP season (May 1) to determine if they had adequate refrigeration to meet these new requirements. If not they were removed (de-listed) from the ICSSL for the period May 1 thru September 30. State of Virginia Shellfish Agencies should be commended for meeting and in several instances exceeding requirements in their Vp Control Plan implementation to reduce the risk of Vp illnesses and outbreaks.
- There was a firm that had been delisted and sent product to another state. Virginia issued a compliance notice to that dealer.
- There was a violation of the 2011 Vp CP for shading of product in which VA Marine Police took action, seized product and the firm was prosecuted and found guilty.
- Virginia has an annual education requirement for all harvesters and disseminates public health information regarding Vibrio risk. This state has requested technical assistance training or educational material development and resources in the area of cooling technology.
- Virginia has a program of icing the oysters onboard the vessels immediately following harvest on the James River and on other areas where state can not monitor you are required to have a GPS tracker that is downloaded by enforcement and this is permitted to validate the hours of harvest based on control plan. Time controls are in place from 10-12 in areas depending on moth. Permits may be issued for exemption of time of day restrictions for landing. All must comply with five hour restriction.
- Any firm that could not meet temperature requirements for cooling to 50 within 10 hours was delisted for the time frame of the VP control plan. May 1 –Sept 30.

Recommendations: In one firm, a pallet of oysters had been pre-chilled to 50 degrees post removal from cooler for final washing and packing. With water temp and time out of the cooler, oysters had warmed to a product temp of 64 degrees F. This was addressed with

firm's manager and procedure for washing the oysters was changed to limit time out of refrigeration.

## **E. State Program Accomplishments**

### **General**

The Virginia State Agencies responsible for regulating and implementing the Vp CP have seen a great deal of progress over the past three years working with their industry and as a team in developing and implementing the VpCP. They were able to promulgate regulations and develop an enforcement program that has proven effective in reaching the goals of the Vp CP.

### **Growing Area Classification Element**

- A joint hydrographic and microbiological study of the James River was conducted during 2010 with FDA, DSS, Hampton Roads Sanitation District, and Virginia Institute of Marine Science.
- DSS staff attended the Interstate Shellfish Sanitation Conference (ISSC) in 2011 in Seattle, Washington. Classification Chief B. Keith Skiles, MPH, participates in the ISSC Executive Committee, ISSC Executive Board.

### **Processing and Shipping Element**

- DSS staff conducted workshops for industry focusing on HACCP and Sanitation Control and Vibrio Illness Control Procedures.
- DSS staff attended the Interstate Shellfish Sanitation Conference in Seattle in October 2011 and actively participated in the Interstate Shellfish Sanitation Conference as a member of Task Force II and as a member of various Committees. Ms. Julie Henderson was elected as the Regulatory representative to the ISSC Region covering VA, MD, DC and DE. Plant Program Manager Julie H. Ray attended and presented at the Interstate Seafood Conference in Ocean City Maryland in September 2010.
- DSS staff developed and helped to implement Virginia's VP CP in partnership with VMRC.
- DSS instituted quarterly training meetings with staff to inform them of upcoming NSSP changes clarify inconsistencies in the program and conduct training.

### **Control of Harvest Element**

- VMRC regulations for harvester tagging became effective January 2011.
- VMRC staff and VDH-DSS staff continue to meet to discuss ongoing issues with "Warm Water Harvest Restrictions" on Shellfish and other issues of concern pertaining to growing areas. Warm Water Harvest regulations for the months of June through September became effective on May 1, 2011.

**F. New or Emerging Findings/Issues**

None noted during this evaluation.

**G. Unresolved Issues**

There are no unresolved issues resulting from the FY 2011 FDA Evaluation of the Virginia Shellfish Sanitation Program administered by the Virginia Department of Health, Division of Shellfish Sanitation and the Virginia Marine Resources Commission, Virginia Marine Police.

**H. Request for Training**

There was a request for training or educational material development and resources in the area of refrigeration and cooling technology by experts in the industry or academia

**I. Acknowledgements**

FDA would like to thank the, Virginia Division of Shellfish Sanitation and the Marine Resources Police for their assistance and efforts during this FY 2011 FDA Evaluation of Vibrio Control Plan implementation Evaluation for the State of Virginia.

FDA would like to thank Dr. Croonenberghs for supporting a strong sanitary plant sanitation and public health element relating to the consumption of raw or uncooked molluscan shellfish in Virginia. FDA RSS Gary Wolf observed that DSS Staff have placed a great deal of effort in achieving the public health standards in Virginia Shellfish facilities relating to illness prevention in general and specifically relating to Vp Controls. They have fostered a good working relationship with the shellfish Dealers to effectively implement the Vp CP in Virginia. FDA finds that the State of Virginia Shellfish Agencies including DSS and MRP have worked together as a team to meet these goals.

Special thanks are offered to Julie Henderson the Plant SSO/Program Manager for this Element and Keith Skiles, Growing Area Classification Manager for arranging the visits to the various Certified Dealers with the field/supervisory staff and the site visits to the harvest area patrols, shoreline surveys and the off-loading docks to observe all of the aspects of the Vp CP implementation. Tim Fearington, John Dickerson, David Geeson and Farah Monis accompanied me to the Plants, the harvest waters and the oyster off-loading docks along with Ms. Henderson and Keith Skiles and all provided me with insight into the implementation of the State's Vp CP and answered all of my questions. All were very knowledgeable of the Vp Control Warm Weather Harvest Regulations as well as the Plants, the Harvest locations and the off-loading, refrigeration, recordkeeping and transport activities.

FDA wishes to thank the VMRC, Virginia Marine Police for working cooperatively with the FDA during this evaluation. Lt. Col. Warner Rhodes and his staff have been very attentive to

NSSP requirements and requiring harvesters to maintain compliance with NSSP regarding the Vp CP .It was very obvious that the MRC/MRP and DSS were working very cooperatively with each other to make this program a success. Our sincere appreciation to Lt. Colonel Warner Rhodes, and Marine Police Officers Captain Jamie Green and Officer Mike Morris for arranging for the FDA to accompany them on patrol activities in shellfish growing waters during the FDA Vp CP evaluation . The officers' knowledge of the area patrolled, the ongoing shellfish harvesting activities and requirements, as well as the local harvesters on the rivers and at the off-loading docks allowed the FDA to understand and observe all aspects of the Virginia Vp CP implementation.