

# Florida Department of Agriculture and Consumer Services

## *Vibrio vulnificus* Risk Management Plan

May 2010 Revision

Charles H. Bronson, Commissioner

### I. Introduction

*Vibrio vulnificus* is a naturally occurring bacterium that is found in marine waters, with the highest numbers found in lower salinity areas including bays and estuaries. Bacterial populations are highest during the warmer months from May to October. Because oysters are filter feeders, *Vibrio vulnificus* bacteria are also commonly found in oysters.

Concerns related to *Vibrio vulnificus* exists because a very small percentage of people who eat raw molluscan shellfish can develop a severe and potentially fatal infection. While healthy individuals with a normally functioning immune system are able to ward off these infections; certain medical conditions put some individuals in a high risk category if they consume raw or inadequately cooked oysters. Conditions for this high risk category include: diabetes, liver impairment (from hepatitis, cirrhosis and alcoholism), cancer, low gastric acid, or prior gastric surgery.

### II. Background

In 2001, delegates at the Interstate Shellfish Sanitation Conference (ISSC) voted to implement a plan to reduce *Vibrio vulnificus* infections related to consumption of raw oysters. The plan established goals for illness rate reduction and required a 40% reduction by 2005-2006 (combined annual average) and a 60% reduction by 2007-2008 (combined annual average) when compared to the baseline years 1995-1999 (combined annual average). The ISSC also established a group of core reporting states which included Texas, Louisiana, Florida and California, where illness rates could be accurately monitored and counted. While the 40% reduction goal was achieved in 2005-2006, the source states fell short of the 60% goal in 2007-2008. The reduction in 2007-2008 was 35.2% or 24.8% short of the goal. Additional action by the ISSC required that source states implement additional controls by May 1, 2010 to achieve the required 60% goal.

The State of Florida, along with other gulf states, is required to update and implement a *Vibrio vulnificus* Risk Management Plan for achieving the 60% goal. Based upon the National Shellfish Sanitation Program (NSSP) requirements passed by the 2001 ISSC, the plan must contain the following required elements:

1. The ISSC Consumer Education Program.
2. Process to collect standardized information for each *Vibrio* illness.
3. A standardized process to track products implicated in *Vibrio* illnesses.
4. Prepare for achieving a goal of post harvest processing capacity of 25% of all oysters intended for raw consumption harvested during the months of May through September by December 31, 2004.
5. Reduce the illness rate by 40% for years 2005 and 2006.

6. Prepare for achieving a goal of post harvest processing capacity of 50% of all oysters intended for raw consumption harvested during the months of May through September by December 31, 2005 should the 40% goal not be achieved.
7. Identification and preparation for implementing additional controls should the 60% reduction in the rate of illness not be achieved collectively for years 2007 and 2008.

The Florida Department of Agriculture and Consumer Services (DACS) is the agency responsible for promulgating public health regulations for oyster harvesting and processing. DACS authority to implement regulatory controls for the Florida *Vibrio vulnificus* Risk Management Plan is contained in 597.020, *Florida Statutes* and 5L-1, *Florida Administrative Code*.

### **III. Required Elements:**

#### **1. Education Program**

The Florida Department of Health (FL DOH), DACS and the ISSC have conducted educational efforts for many years in Florida. On-going efforts have included yearly press releases warning at risk consumers not to consume raw oysters, and distributing educational pamphlets in Spanish and English at various events in the state.

These educational tools include educational pamphlets in Spanish and English, physician fact sheets, education videos for clinicians, public service announcements and media press sets. Florida has used the tools provided by the efforts of the ISSC whenever possible. Within FL DOH and DACS, partnerships were developed between associates that deal directly with risk groups such as those involved in diabetes, hepatitis and HIV education and with any continuing education activities for physicians, nurses, epidemiologists or other health care professionals. DACS continued partnership with the FL DOH Division of Disease Control is essential to a successful program. Outside of FL DOH, partnerships have been longstanding with DACS to include the warning to at risk individuals in their promotional efforts and the University of Florida Marine Sea Grant and Extension Program.

The ISSC *Vibrio vulnificus* Management Committee (VMC) has provided guidance on what program elements should be contained in a state education program. Elements should address education to high risk consumers, health professionals and broader consumer audience.

Educational efforts in Florida regarding the risk of raw oyster consumption and *Vibrio vulnificus* is provided in attachment 1.

#### **2. Standardized Process to Collect Information for Each *Vibrio vulnificus* Illness**

A workgroup of the ISSC developed an addendum to the Center for Disease Control and Prevention (CDC) *Vibrio* investigation form (COVIS form). The CDC COVIS form and addendum will be used by the core states (TX, LA, FL, CA) to gather standardized information on *Vibrio vulnificus* infections. FL DOH uses the CDC COVIS form and addendum to report all *Vibrio* illnesses and this form ensures the standardized collection of information related to *Vibrio vulnificus* illnesses.

### **3. A standardized process to track products Implicated in *Vibrio vulnificus* illnesses**

FL DOH utilizes the CDC COVIS form and addendum. Data related to the tracking of the product back to the certified dealer(s) is included within the COVIS form. DACS inspects all dealers who are implicated in a *Vibrio* illness to identify harvest dates and areas, review HACCP records, identify any sanitation problems, and verify that the harvest area was in the "open" status at the time of harvest. Information collected during these inspections is recorded in a DACS illness investigation report. Retailers implicated in a *Vibrio* illness are also inspected by the appropriate regulatory authority (DACS Division of Food Safety or the Florida Department of Business and Professional Regulation).

### **4. Prepare for achieving a goal of post harvest processing (PHP) capacity of 25% of all oysters intended for raw consumption harvested during the months of May through September by December 31, 2004.**

Several PHP have been demonstrated to significantly reduce *Vibrio vulnificus*. It is thought that increasing the percentage of PHP oysters in the market place will result in a decrease in illnesses. This logic is based on the assumption that PHP oysters have equivalent market acceptance to live, untreated oysters. Several types of PHP processes have demonstrated the ability to significantly reduce *Vibrio vulnificus*. High pressure treatment, irradiation, mild heat pasteurization, and low temperature treatment with extended frozen storage have each demonstrated significant *Vibrio vulnificus* level reductions in oysters. Market acceptance of post harvest processes product is essential if these processes are to be effective in reaching the illness reduction goal.

On December 31, 2004, the Florida oyster industry exceeded the 25% PHP processing capacity requirement. The survey report was provided to the ISSC. Since December 31, 2004 the Florida oyster industry has exceeded the 25% PHP capacity based upon the number of firms in Florida validated for PHP and Florida May through October oyster landings.

### **5. Prepare for achieving a goal of PHP capacity of 50% of all oyster intended for raw consumption harvested during the months of May through September by December 31, 2006 if a 40% illness reduction goal is not achieved.**

The 40% illness reduction goal was achieved collectively by the core states, which eliminated this requirement. However, since December 31, 2006, the Florida oyster industry has exceeded 50% PHP capacity based upon the number of firms in Florida validated for PHP and Florida May through September oyster landings.

### **6. Identification and preparation for implementation of one or more of the following controls or equivalent controls which shall be implemented should the 60% rate of illness not be achieved collectively by 2008. The adjustment to the States plan can take into account the illness rate reduction that has occurred since the last review of the plan.**

(a) Labeling all oysters, "For shucking by a certified dealer", when the average monthly water temperature exceeds 75 degrees.

(b) Subjecting all oysters intended for the raw, half shell market to an approved post harvest processing that reduces the Vv to less than 30 MPN/gram when the water temperature exceeds 75 degrees.

(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for raw, half shell market when the average monthly maximum water temperature exceeds 75 degrees.

(d) Labeling all oysters, "For shucking by a certified dealer", during the months of May-September inclusive;

(e) Subjecting all oysters intended for raw the raw, half shell market to a post harvest process that is both approved and reduces Vv levels to less than 30 MPN /gram during the months of May through September.

(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half shell market during the months of May through September, inclusive.

#### **IV. Current Status / Planning for Implementation of New Controls**

In 2001, ISSC Delegates voted to implement a plan to reduce *Vibrio vulnificus* infections related to consumption of raw oysters. The plan established goals for illness rate reduction. The plan required a 40% reduction in 5 years and a 60% reduction in 7 years reported from Texas, Louisiana, Florida and California. In subsequent action by the ISSC, the illness rate reduction of 60% was to be compared against the core states illness rates averaging 2007 and 2008. The actual illness reduction rate achieved was determined by the ISSC to be 35.2%. Additional action by the ISSC required that source states implement controls by May 1, 2010 to achieve the additional 24.8% illness rate reduction to achieve the required 60% goal. In 2009, the source states presented to the VMC additional "time temperature" controls that are predicted to achieve the additional required 24.8% illness rate reduction. This prediction is based on the use of the US FDA *Vibrio vulnificus* risk calculator.

The following sections of this document describe the additional controls proposed by DACS to achieve the required 60% illnesses rate reduction and the administrative process to be used in establishing those controls.

Representatives from Texas, Louisiana, Mississippi, Alabama and Florida agreed on the basic outlines of the *Vibrio vulnificus* Management Plan. The Gulf States used the US FDA approved Vibrio Risk Calculator as a tool to guide decision making on the Plan, but did not limit themselves to the Vibrio Risk Calculator.

The core component of the new *Vibrio vulnificus* Management Plan is a Gulf-wide average target of approximately 9 illnesses per year in the core states, annual average for the 2010 - 2011 reporting period.

The *Vibrio vulnificus* Management Plan also gives the Gulf states flexibility to work with the industry and individual harvesters to explore and implement equivalent new methods for PHP

and Post-Harvest Handling (PHH) to achieve the illness rate reduction goals of the *Vibrio vulnificus* Management Plan.

The Management Plan has two core components:

- a) Significant reductions in Maximum Time Unrefrigerated and Maximum Time to Cool down during each year, based on the VV Risk Calculator, or:
- b) other state-specific components which can be shown to meet the illness target using the Risk Calculator as an evaluation tool.

Assumptions used with the calculator:

1. It is assumed that 15% of the harvest is PHP, therefore, the number of servings were reduced by 15%.
2. The risk assessment assumes that consumption of raw oysters by at risk consumers is the same as consumers not-at-risk. The ISSC education survey indicates a 6% reduction of consumption by at risk consumers, which is not currently incorporated in the Vv Calculator.
3. The controls will affect harvest levels. It is estimated that the controls will result in a ten to twenty percent reduction of harvest (servings). The calculator uses the more conservative ten percent estimate.

DACS provided the VMC measures necessary to achieve the 60% NSSP illness rate reduction goal using significant reductions in maximum time unrefrigerated and maximum time to cool down based on the US FDA *Vibrio vulnificus* Risk Calculator and the assumptions developed at the Gulf State meeting.

Baseline entries in the US FDA *Vibrio vulnificus* Risk Calculator:

- The baseline “water temperature (F)” entries in the US FDA *Vibrio vulnificus* Risk Calculator are Florida specific and are identical to the temperatures used for the Apalachicola Bay Shellfish harvesting area for the *Vibrio parahaemolyticus* harvest controls modeled using the US FDA Vp Calculator and approved by the U.S. Food and Drug Administration during the Florida 2008 program evaluation.
- The “Baseline air temperature during harvest (F)” entries in the US FDA *Vibrio vulnificus* Risk Calculator are average hourly temperatures from sunrise to sunset from data loggers in the Apalachicola Bay Shellfish harvesting area.
- The “Baseline maximum time unrefrigerated (hrs)” entries in the US FDA *Vibrio vulnificus* Risk Calculator are the harvesting regulations in place in Florida during the baseline years. During the baseline years (and currently), “the maximum time unrefrigerated” in April through October can be any continuous subset of time between sunrise and sunset.
- Unchanged are the US FDA “Baseline maximum time to cooldown (hrs)” entries in the US FDA *Vibrio vulnificus* Risk Calculator.
- Unchanged are the US FDA “Baseline # of servings” in the US FDA *Vibrio vulnificus* Risk Calculator.

Model entries in the US FDA *Vibrio vulnificus* Risk Calculator:

- The “air (oyster) temperature during harvest (hrs)” entries in the US FDA *Vibrio vulnificus* Risk Calculator for the months of May through October are sunrise to five hours after sunrise average hourly temperatures using data from the same time period and locations as was used for the “Baseline air temperature during harvest (F)” entries. This modeled control reduces the available harvest window by a minimum of 62% (from the current sunrise to sunset window of approximately 13 hours to the proposed sunrise to less than five hours after sunrise harvest window).
- The “maximum time unrefrigerated (hrs)” entries in the US FDA *Vibrio vulnificus* Risk Calculator for the months of May through October are less than 5 hours. However, 5 hour maximum time unrefrigerated was entered into the model. This modeled control reduces the maximum time unrefrigerated in May and October by a minimum of 58% (from the current 12 hours to the proposed less than 5 hours).
- The “maximum time to cooldown (hrs)” entries in the US FDA *Vibrio vulnificus* Risk Calculator for the months of May through October are 8 hours. This modeled control reduces the maximum time to cooldown by 20% (from the current 10 hours to the proposed 8 hours).
- The “# of servings” entries in the US FDA *Vibrio vulnificus* Risk Calculator include a 15% reduction for PHP for all months (see Gulf States Meeting).
- The “# of servings” entries in the US FDA *Vibrio vulnificus* Risk Calculator include a 10% reduction in harvest due to proposed controls in May through October (see Gulf States Meeting).
- The “# of servings” entries in the US FDA *Vibrio vulnificus* Risk Calculator do not include a 6% reduction (or any other percentage) in harvest due to the NSSP education program (see Gulf States Meeting).

US FDA *Vibrio vulnificus* Risk Calculator output is provided in attachment 2.

#### **V. DACS estimated time to implement control measures:**

DACS must adopt the final measures by rule according to the *Florida Administrative Procedures Act*. DACS began the rulemaking process on October 26, 2009 so that the measures can be become effective by May 1, 2010. Notes: Important things to consider about the *Florida Administrative Procedures Act*. (1) all agency rulemaking is reviewed during all official steps by the Florida Legislature’s Joint Administrative Procedures Committee, State of Florida Small Business Regulatory Advisory Council and Office of Tourism, Trade and Economic Development, (2) established rulemaking processes must be strictly followed, (3) public input is required, (4) proposed equivalent alternatives must be considered, (5) economic impacts may be requested, (6) notices or change can be requested resulting in slight delay in effective date, and (7) proposed agency rules that are challenged are stayed until the resolution of the challenge. DACS and the Florida oyster industry are bound by the *Florida Administrative Procedures Act*. DACS previously requested from the ISSC economic impact information related to regulations for controls for *Vibrio vulnificus*, and the information provided by the ISSC was deemed insufficient.

## **VI. DACS interim steps that will be used to achieve implementation by May 1, 2010.**

DACS is committed to implementing additional time to temperature controls described in this *Vibrio vulnificus* Risk Management Plan by May 1, 2010. The implementation of these controls requires revisions to Rule 5L-1, *Florida Administrative Code* entitled *Comprehensive Shellfish Control Code*. A request to initiate the rule making process and publish a Notice of Proposed Rule Development was initiated on October 26, 2009. Approval for publication of the Notice of Proposed Rule Development was received on November 1, 2009. The Notice of Proposed Rule Development was published in the *Florida Administrative Weekly* on November 13, 2009. After the mandated 14-day waiting period, a series of 7 rule development workshops for affected parties were held across the state from November 30, 2009 through December 10, 2009. Workshop comments were summarized, written comments were received and reviewed. Changes were incorporated into the proposed rule amendments and on February 1, 2010 a request was submitted to the Commissioner of Agriculture and Consumer Services for approval for publication of the Notice of Proposed Rule. On February 11, 2010, permission was granted. Upon this approval, economic impact statements were prepared and sent to the Office of Tourism, Trade and Economic Development, the Small Business Regulatory Advisory Council and the Joint Administrative Procedures Committee, as required by *Florida statutes*. The Notice of Proposed Rule was submitted to *Florida Administrative Weekly* on February 15, 2010 and subsequently published on February 26, 2010 in *Florida Administrative Weekly*. Three public hearings on the rule were held on March 19, 22, and 23 in affected areas. Following the public hearings the rule amendment package was submitted for final review and approval by the Commissioner of Agriculture and Consumer Services on April 1, 2010 and the rule was approved and filed with the Department of State on April 6, 2010. There were no challenges to the rule filed during the 20 day waiting period and the rule became effective on April 26, 2010.

DACS has developed a "Guidance for Implementation of Rule 5L-1.008(5),(6),(7),(8),and (9), F.A.C." document (Attachment 7) to provide clear guidance to the oyster industry on the processes to be used in completing validation testing required by the rule. The document also includes a "Suggested Time to Temperature Validation Reporting Format" that can be used by oyster dealers to report validation testing results to DACS. The University of Florida has agreed to provide industry technical assistance in validating the new time and temperature controls. All oyster processors handling oysters must validate their cooling systems capable of achieving cooldown to 55 degrees Fahrenheit or less within 8-hour or less. Oysters not meeting these new time temperature controls can be: (1) shucked by a certified processor, and/or (2) Post Harvest Processed by a system validated by DACS for *Vibrio vulnificus*.

DACS has also developed model Hazard Analysis Critical Control Point (HACCP) plans (Attachment 8) for oyster processors who are purchasing: 1) Traditionally Harvested Oysters (morning harvest), 2) Oysters harvested under the rules for Complete On-board Cooling, 3) Oysters harvested under the rules for Partial On-board Cooling, or 4) Oysters harvested under the rules for Rapid Cooling. During the month of May, 2010, all Florida oyster processors are required to update their HACCP Plans in accordance with the new rules. Oyster processors who need assistance with this process are strongly encouraged to contact their DACS Inspector to request this assistance.

The NSSP *Vibrio vulnificus* Management Plan gives the Gulf States flexibility to work with the individual oyster processors/harvesters to explore and implement equivalent new methods for Post-Harvest Processing (PHP) and Post-Harvest Handling (PHH) to achieve the illness rate reduction goal of the NSSP *Vibrio vulnificus* Management Plan.

DACS *Vibrio vulnificus* Risk Management Plan provides for equivalent options for rapid cool down at the processor and on-board cooling, using the US FDA *Vibrio vulnificus* Risk Calculator tool to achieve the level of risk associated with the time to temperature requirements listed above.

### **Option 1 - Complete On-board Cooling.**

Oyster harvesters using this option will: 1) be limited to a maximum time unrefrigerated of 1 hour, 2) utilize an on-board cooling system capable of cooling oysters to 55 degrees within 9 hours, and 3) deliver oysters to a certified dealer by 4:00pm on the day of harvest. DACS recognizes that oysters harvested under this option will be delivered to the dealer at various temperatures depending on the time of harvest.

All oyster processors in Florida will be required to utilize a cooling system capable of completely cooling oyster to 55 degrees Fahrenheit within 8 hours regardless of the starting temperature. Oyster processors receiving oysters under this option will also have to identify harvesters delivering completely cooled oysters in their HACCP plan and will have to establish additional record keeping requirements including, but not limited to, time of receiving from each harvester and the temperature of the first bag harvested each day.

US FDA *Vibrio vulnificus* Risk Calculator for Complete On-board Cooling is provided in Attachment 3.

### **Option 2 – Partial On-board Cooling**

Oyster harvesters using this option will: 1) be limited to a maximum time unrefrigerated of 1 hour, 2) utilize an on-board cooling system capable of cooling oysters to 65 degrees within 7 hours, and 3) deliver oysters to a certified dealer by 3:00pm on the day of harvest. DACS recognizes that oysters harvested under this option will be delivered to the dealer at various temperatures depending on the time of harvest.

All oyster processors in Florida will be required to utilize a cooling system capable of completely cooling oyster to 55 degrees Fahrenheit within 8 hours regardless of the starting temperature. For this reason, an oyster dealers cooling system will have enough cooling capacity so that all oysters handled under the partial cooling option will be cooled to 55 degrees within 10 hours of the time of harvest. Oyster processors receiving oysters under this option will also have to identify harvesters delivering partially cooled oysters in their HACCP plan and will have to establish additional record keeping requirements including, but not limited to, the time of receiving from each harvester and the temperature of the first bag harvested each day.

US FDA *Vibrio vulnificus* Risk Calculator for Partial On-board Cooling is provided in Attachment 4.

**Option 3 - Rapid Cooling**

Oyster harvesters using this option will deliver oysters to a certified dealer by 2:00pm on the day of harvest. Oyster dealers using this option will cool oysters to 55 degrees within 2 hours. Oyster processors receiving oysters under this option will also have to identify harvesters delivering oysters for rapid cooling in their HACCP plan, and will have to establish additional record keeping requirements including, but not limited to, the time of receiving from each harvester.

US FDA *Vibrio vulnificus* Risk Calculator for Rapid Cooling is provided in Attachment 5.

Attachment 1. Educational Efforts by the State of Florida Regarding the Risk of Raw Oyster Consumption and *Vibrio vulnificus* (updated March 1, 2010)

	<b>Year</b>	<b>Educational Activity</b>
1.	1988	Florida has utilized the CDC COVIS form since it was created. Data related to the tracking of the product is included within the COVIS form. Therefore by using the COVIS form, Florida uses a standardized process to track products implicated in Vv illnesses.
2.	1988	<p>The Florida Department of Health (FL DOH), the Florida Department of Agriculture and Consumer Services (FDACS) and the ISSC have conducted educational efforts for many years in Florida. On-going efforts have included yearly press releases warning at risk consumers not to consume raw oysters, and distributing educational pamphlets in Spanish and English at various events in the state.</p> <p>These educational tools include educational pamphlets in Spanish and English, physician fact sheets, education videos for clinicians, public service announcements and media press sets. Florida has used the tools provided by the efforts of the ISSC whenever possible. Within FL DOH and FDACS, partnerships were developed between associateships that deal directly with risk groups such as those involved in diabetes, hepatitis and HIV education and with any continuing education activities for physicians, nurses, epidemiologists or other health care professionals. Continued partnership with the FL DOH Division of Disease Control is essential to a successful program. Outside of FL DOH, partnerships have been longstanding with FDACS to include the warning to at risk individuals in their promotional efforts and the University of Florida Marine Sea Grant and Extension Program.</p> <p>The ISSC <i>Vibrio vulnificus</i> Management Committee has provided guidance on what program elements should be contained in a state education program. Elements should address education to high risk consumers, health professionals and broader consumer audience. The list below describes educational activities by year conducted by FL DOH and FDACS in Florida.</p>
3.	1988	Joint State of Florida food Agencies and FDA Workshop to educate the shellfish industry on <i>Vibrio vulnificus</i> .
4.	1988	Florida Department of Natural Resources press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.
5.	1988	Annals of Internal Medicine, 109:318-323, 1988 – Syndromes of <i>Vibrio vulnificus</i> infections: clinical and epidemiologic features in Florida cases, 1981-1987 (Klontz, KC et al.).
6.	1989	Brochure titled " <i>Vibrio vulnificus</i> an Advisory Note", University of Florida Food Science and Human Nutrition Department. Provided to Florida health agencies and Florida oyster industry for distribution to the public.
7.	1989	Florida Department of Natural Resources press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.

	Year	Educational Activity
8.	1990	Letter from David Heil, Florida Department of Natural Resources the Editor Florida Journal of public Health alerting physicians of the risk of <i>Vibrio vulnificus</i> to high-risk individuals.
9.	1990	Florida Department of Natural Resources press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.
10.	1991	American Journal of Epidemiology, 1991, 134(3):290-297 – The Risk of Vibrio Illness in the Florida Raw Oyster Eating Population, 1981-1988 (Desenclos, Jean-Claude A., et al.)
11.	1991	Epidemiology, November, 1991, 2(6):437-440 – The Raw Oyster Consumer – A Risk Taker? Use of the Behavioral Risk Factor Surveillance System (Klontz, Karl C. et al.)
12.	1991	Epidemiology, November, 1991, 2(6):401-402 – The Value of an Indirect Index in Selecting Groups for a Health Education Message (Philip Cole)
13.	1991	Voluntary adoption of Consumer Information statement on shellstock and shucked oyster containers by selected Florida oyster industry members.
14.	1991	Florida Department of Natural Resources press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.
15.	1992	Volume 13, Issue 5, September 1992 – HRS Epi Gram: Seven Deaths Result from Eating Raw Oysters
16.	1992	Volume 13, Issue 6, November 1992 – HRS Epi Gram: <i>Vibrio vulnificus</i> Infections Associated with Raw Oyster Consumption, Florida, 1981-1992
17.	1992	HRS Health Advisory, December 9, 1992 – Warning regarding the consumption of raw oysters
18.	1992	Training by the Florida Department of Natural Resources and Florida Sea Grant of approximately 375 state food inspectors in the state of Florida in proper shellfish sanitation techniques.
19.	1992	Florida Department of Natural Resources press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.
20.	1993	Department of Business Regulation Industry Advisory, February 11, 1993 – Raw Oysters: Health Risk
21.	1993	Ongoing - Restaurant warning: s. 64D-3.013(7), Florida Administrative Code: “All food service establishments serving raw oysters shall display, either on menus, table placards, or elsewhere in plain view of all patrons, the following notice: “There is a risk associated with consuming raw oysters. If you have chronic illness of the liver, stomach or blood or have immune disorders, you are at greater risk of serious illness from raw oysters, and should eat oysters fully cooked. If unsure of your risk, consult a physician.”” In effect since June 24, 1993 (Emergency Rule, Final Rule in effect: November 1, 1994).
22.	1993	Ongoing - Shellfish Processor warning: s. 5L-1.007(10), Florida Administrative Code: “Oyster shellstock and shucked oyster containers shall be labeled with the following statement: “CONSUMER INFORMATION There is a risk associated with consuming raw oysters. If you have chronic illness of the liver, stomach or blood or have immune disorder, you are at greater risk of serious illness from raw oysters and should eat oysters fully cooked. If unsure of your risk, consult a physician.””

	Year	Educational Activity
23.	1993	Ongoing - Retail seafood market warning: Ch. 500, F.S., "Oyster shellstock and shucked oyster containers shall be labeled with the following statement: "CONSUMER INFORMATION There is a risk associated with consuming raw oysters. If you have chronic illness of the liver, stomach or blood or have immune disorder, you are at greater risk of serious illness from raw oysters and should eat oysters fully cooked. If unsure of your risk, consult a physician."
24.	1993	HRS Press Release, September 2, 1993 – Florida Visitor Succumbs to <i>Vibrio vulnificus</i> , HRS to Hold a Public Hearing on Oyster Warning Rule
25.	1993	Journal of Food Protection, November, 1993, 56(11):977-979 – Raw Oyster-Associated <i>Vibrio</i> Infections: Linking Epidemiologic Data with Laboratory Testing of Oysters Obtained from a Retail Outlet (Klontz, Karl C. et al.)
26.	1993	Morbidity and Mortality Weekly Report (MMWR), 42:405-407, 1993 – <i>Vibrio vulnificus</i> infections associated with raw oyster consumption, Florida, 1981-1982.
27.	1993	Florida Department of Natural Resources press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.
28.	1994	HRS <i>Vibrio vulnificus</i> brochure – distributed to each of the state's 67 County Health Departments and nine regional food and waterborne disease epidemiologists for issuance to clients, and upon request for information (copies remain, but the pamphlet is now are outdated due to agency reorganization).
29.	1994	Joint Florida State University/University of Florida Pilot Project funded by the Gulf of Mexico Program educating approximately 700 health care professionals in Florida and other Gulf states locations (Seafood Poisoning and the High Risk Patient at a meeting of the Florida Nurses Association, Tallahassee, March 1994).
30.	1994	Ongoing - Since 1994, the Annual Report of Foodborne Illness in the State of Florida discusses the number of cases and deaths due to <i>Vibrio vulnificus</i> (shellfish consumption related as well as wound infection and unknown exposure). In numerous public presentations to health professionals, <i>Vibrio vulnificus</i> is often discussed (topics include: clinical syndromes, high risk consumers, numbers of cases and deaths for the current and previous year, difficulties in reaching high risk categories of consumer).
31.	1994	HRS Press release, September 12, 1994 – Death From Raw Oysters is Seventh of Season
32.	1994	Department of Business and Professional Regulation – Industry Advisory to Public Food Service Establishments (#94-001) – Raw Oysters Health Risk – September 16, 1994
33.	1994	Journal of the Florida Medical Association, 80(8):536-538, August, 1993 – <i>Vibrio vulnificus</i> from Raw Oysters – Leading cause of reported deaths from foodborne illness in Florida (W. Gary Hlady, et al.)
34.	1994	Florida Department of Health and Rehabilitative Services, Florida Department of Agriculture and Consumer Services, and Florida Department of Environmental Protection press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.
35.	1995	<i>Vibrio vulnificus</i> education focus groups (Tampa, FL and New Orleans, LA, April-July, 1995) – Summary report (CFSAN/FDA)

	<b>Year</b>	<b>Educational Activity</b>
36.	1995	Florida Department of Health and Rehabilitative Services, Florida Department of Agriculture and Consumer Services, and Florida Department of Environmental Protection press release to approximately 600 media contacts in the state of Florida alerting high risk consumers of the hazards of <i>Vibrio vulnificus</i> infection due to raw oyster consumption and contact with seawater.
37.	1995	Implementation into rule the harvesting controls suggested by the Interstate Shellfish Sanitation Conference Consumer Protection Committee.
38.	1995	Florida Department of Health Annual Food and Waterborne Illness Report
39.	1996	Implementation into rule the Interstate Shellfish Sanitation Conference <i>Vibrio vulnificus</i> Matrix.
40.	1996	Pearls of Wisdom for Oyster Lovers – The Complete Trainer’s Guide on the Prevention of <i>Vibrio vulnificus</i> Infection (Pasco County Health Department) – Guide distributed to all 67 of Florida’s County Health Departments and to each of the nine regional food and waterborne disease epidemiologists in the Department of Health to use in training with County Health Department staff and other community groups.
41.	1996	Florida Journal of Environmental Health, February, Issue 153:6-9 – Ecology and Virulence of Halophilic Vibrios in Florida, Erin Lipp and Roberta Hammond
42.	1996	Journal of Infectious Diseases, 173:1176-1183, May, 1996 – The Epidemiology of Vibrio Infections in Florida, 1981-1993 (W. Gary Hlady and Karl Klontz)
43.	1996	Florida Department of Health Annual Food and Waterborne Illness Report
44.	1997	Journal of Food Protection, 60(4):353-357, 1997 – Vibrio Infections Associated with Raw Oyster Consumption in Florida, 1981-1994 (W. Gary Hlady)
45.	1997	Water-related Disease in Florida: Continuing Threats Require Constant Vigilance, Richard Hopkins, MD, MSPH, Sharon Heber, MPH, Roberta Hammond, PhD, The Journal of the Florida Medical Association, Inc., October, (84)7:441-445.
46.	1997	Florida Department of Health Annual Food and Waterborne Illness Report
47.	1998	Journal of Infectious Diseases, September, 1998 (178)3:752-759 – The Role of Gulf Coast Oysters Harvested in Warmer Months in <i>Vibrio vulnificus</i> Infections in the United States, 1988-1996 (R.L. Shapiro et al.)
48.	1998	Adoption into rule Hazard Analysis Critical Control Point (HACCP) regulations for Florida shellfish processors.
49.	1998	Florida Department of Health Annual Food and Waterborne Illness Report
50.	1999	<i>Vibrio vulnificus</i> : Not A Pearl You Want To Find, National Laboratory Training Network (NLTN):, February 26, 1999 (Mark Tamplin, coordinator) – satellite broadcast, February 26, 1999, Gainesville, FL. Copies of the broadcast were made and sent to each of the nine regional food and waterborne disease epidemiologists in the Department of Health to use in training with County Health Department staff who were unable to view the original broadcast.

	Year	Educational Activity
51.	1999	<i>Vibrio vulnificus</i> Model Education Campaign (ISSC) – in Florida, 3 population areas were targeted: Jacksonville, Tampa and Miami-Dade. Surveys and fact sheets were disseminated by the Department of Health “to a broad spectrum of clinicians including physicians, nurses, health educators and dieticians.” Target specialties included “infectious disease, gastroenterology, internal medicine, emergency medicine, hematology and oncology.” Surveys and fact sheets were also sent to “nurses specializing in chemical dependency, critical care, and gerontology; health educators working in licensed hospitals; Health Education Councils, and the Florida Dietetic Association.” Along with each professional fact sheet and survey, @ 5 patient educational kits were included.
52.	1999	Department of Business and Professional Regulation – Hospitality Education Program brochure (DBPR Form 5025-409) – <i>Vibrio vulnificus</i> and Raw Oysters: Are You at Risk?
53.	1999	Florida Environmental Health Association (FEHA) developed a video PSA: Shellfish Precaution
54.	1999	Florida Department of Health Annual Food and Waterborne Illness Report
55.	2000	Department of Business and Professional Regulation - Important Information for Florida’s Hospitality Industry (#2000-01)– Raw Oysters Health Risk – 2000
56.	2000	Distribution of more ISSC <i>Vibrio vulnificus</i> pamphlets (American Liver Foundation – Gulf Coast Chapter, Notice in week of June 28, 2000 Epi Update, Department of Health Epidemiology newsletter): To all Florida County Health Department directors and administrators for distribution to help educate high-risk individuals about the dangers of eating raw shellfish with other mailings going to Florida transplant centers, gastroenterologists, support groups, and the Gulf Coast Chapter general mailing list.
57.	2000	Florida Department of Health Annual Food and Waterborne Illness Report
58.	2001	Department of Agriculture and Consumer Services received a United State Environmental Protection Agency, Gulf of Mexico Program grant to conduct a <i>Vibrio vulnificus</i> educational seminar, including a display, at the Florida Medical Association annual meeting, September 22, 2001.
59.	2001	Florida Department of Health received funding from the Interstate Shellfish Sanitation Conference to conduct <i>Vibrio vulnificus</i> training to educate nurses and registered dieticians and develop training materials for food handlers at the retail level focusing on time/temperature issues and raw oysters.
60.	2001	Florida Department of Health Annual Food and Waterborne Illness Report
61.	2002	The Florida Nurse (50)1:28, March, 2002 - <i>Vibrio vulnificus</i> and the High Risk Patient: A Potentially Fatal Disease. Distributed to 175,000 members.
62.	2002	Article submitted April 18 to DBPR for Food Service Education Quarterly newsletter, also posted on their website.
63.	2002	Florida Department of Health developed and presented <i>Vibrio vulnificus</i> training for restaurant inspectors, videotaped and to be presented to restaurant inspectors statewide. April, 19.
64.	2002	DOH press release, May 2.
65.	2002	ISSC press kits sent to major TV affiliates in Florida, May.
66.	2002	Article submitted to Florida Dietetic Association for publication in their quarterly newsletter, June 4.
67.	2002	DBPR brochure finalized June 4. Hand-delivered to oyster-serving restaurants.

	<b>Year</b>	<b>Educational Activity</b>
68.	2002	May-June. DOH contacted Florida liver support groups and sent ISSC brochures out to groups in English and Spanish.
69.	2002	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, with ISSC display (display dates: July 14-17) presented at the Annual Meeting of the Florida Dietetic Association, Ft. Lauderdale, July 16.
70.	2002	Train-the-Trainer workshop for Regional Food and Waterborne Disease Epidemiologists, Orlando, September 17.
71.	2002	Florida Student's Nursing Association 2002 Annual Convention Display, Orlando, September 12-13.
72.	2002	ISSC Display – USDA Food Safety Educator's Conference, Orlando, September 18-21.
73.	2002	Florida Department of Agriculture and Consumer Services (DACs) Agreement with Winn Dixie pharmacies to distribute <i>Vibrio vulnificus</i> information to high risk patients with their prescriptions (start date TBA)
74.	2002	Florida Department of Health Annual Food and Waterborne Illness Report
75.	2003	Gulf Oyster Industry Council Annual Meeting – Status of Florida's <i>Vibrio vulnificus</i> Educational Efforts, January 12.
76.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Nurses, presented to the Hillsborough Chapter of the Florida Nurses Association, Tampa, January 14.
77.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment, presented (2x) at the Florida Department of Environmental Health Directors Meeting, Tampa, January 27.
78.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to the Cypress Chapter of the Florida Dietetic Association, Winter Haven, January 30.
79.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Nurses, presented to the Broward Chapter of the Florida Nurses Association, Ft. Lauderdale, February 3.
80.	2003	<i>Vibrio vulnificus</i> Education in Florida and <i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to a University of North Florida nutrition class, Jacksonville, February 10.
81.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to the Manasota chapter of the Florida Dietetic Association, Venice, February 18.
82.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to the Gainesville chapter of the Florida Dietetic Association, Gainesville, March 11.
83.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to the Broward chapter of the Florida Dietetic Association, Ft. Lauderdale, March 15.
84.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, presented to staff of the Lakeland Regional Medical Center, Lakeland, March 19.
85.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, presented to staff of the Broward County Health Department, Ft. Lauderdale, March 20.
86.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, presented at the Southeast Regional Epidemiology Meeting, Miami, March 28.
87.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to Ft. Lauderdale Culinary Arts Institute, Ft. Lauderdale, April 16.
88.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, presented to staff of the Franklin County Health Department, Apalachicola, April 25.
89.	2003	Press release: Department of Health Reminder About Potential Risk of Eating Raw Oysters, May 1.

	Year	Educational Activity
90.	2003	<i>Vibrio vulnificus</i> Education in Florida and <i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to staff of the Duval County Health Department, Jacksonville, May 19.
91.	2003	Rule change - s. 64D-3.013(7), F.A.C.: <i>Vibrio</i> infections. All food service establishments serving raw oysters shall display, either on menus, <u>or</u> table placards, <del>or elsewhere in plain view of all patrons</del> , the following notice: "Consumer Information: There is risk associated with consuming raw oysters. If you have chronic illness of the liver, stomach or blood or have immune disorders, you are at greater risk of serious illness from raw oysters, and should eat oysters fully cooked. If unsure of your risk, consult a physician." Effective June 9, 2003.
92.	2003	<i>Vibrio vulnificus</i> Education in Florida and <i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to the Pinellas chapter of the Florida Dietetic Association, St. Petersburg, May 21.
93.	2003	Florida <i>Vibrio vulnificus</i> display at the Annual Meeting of the Florida Dietetic Association, Naples, July 14-15.
94.	2003	Florida <i>Vibrio vulnificus</i> display and poster during National Food Safety Month at Prather Building, Southwood Office Complex, Tallahassee, September 2-15 and EATZ Cafeteria, Southwood Office Complex, Tallahassee, September 16-30.
95.	2003	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, presented to staff of the St. Johns County Health Department, St. Augustine, September 18.
96.	2003	<i>Vibrio vulnificus</i> Education in Florida and <i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Dieticians, presented to the East Central chapter of the Florida Dietetic Association, Orlando, September 25.
97.	2003	Telemundo TV Interview on <i>Vibrio vulnificus</i> and other public health topics, Miami, September 26.
98.	2003	Florida <i>Vibrio vulnificus</i> display and poster at the Safety Expo 2003, Southwood Office Complex, Tallahassee, October 1 and Florida Capitol, Tallahassee, October 15.
99.	2003	Florida <i>Vibrio vulnificus</i> display and poster at the Southeast Regional Food and Drug Administration Annual Meeting, St. Augustine, October 20-24.
100.	2003	Florida <i>Vibrio vulnificus</i> display at Department of Health Basic Environmental Health training, Tallahassee, October 27-31.
101.	2003	Florida <i>Vibrio vulnificus</i> poster at Regional Epidemiology Seminar, Daytona Beach, October 29-30.
102.	2003	Florida Department of Health Annual Food and Waterborne Illness Report
103.	2004	<i>Vibrio vulnificus</i> poster on display at Duval, Baker, and Clay CHDs from January 14 – April 19.
104.	2004	<i>Vibrio vulnificus</i> poster on display at 3 Nassau County Health Department clinics from April 23 – June 18.
105.	2004	<i>Vibrio vulnificus</i> Train-the-Trainer Workshop, New Orleans, April 13.
106.	2004	Press release: Department of Health Reminder About Potential Risk of Eating Raw Oysters, May 28.
107.	2004	A workgroup of the <i>Vibrio vulnificus</i> subcommittee developed an addendum to the CDC <i>Vibrio</i> investigation form (COVIS). The addendum will be used by the core states (TX, LA, FL, CA) to gather standardized information on <i>Vibrio vulnificus</i> infections. Florida has used the COVIS form since it was created.
108.	2004	Florida <i>Vibrio vulnificus</i> display and poster at the Annual Meeting of the Florida Dietetic Association, Palm Beach Gardens, July 12-13.

	Year	Educational Activity
109.	2004	Florida <i>Vibrio vulnificus</i> display and poster at the Florida Public Health Association/Florida Association of Public Health Nurses/Florida Environmental Health Association 2004 Joint Annual Educational Meeting and Trade Show, Orlando, July 29.
110.	2004	FAMU Student rotation project. DOH contacted Florida liver support groups and sent ISSC brochures out to groups in English and Spanish. July.
111.	2004	<i>Vibrio vulnificus</i> display and poster at the 2004 Summer Symposium of the Academy of Florida Physican's Assistants, Florida Marco Island, August 4-7
112.	2004	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, presented to the 2004 Annual Summer Symposium of the Florida Academy of Physician's Assistants, Marco Island, August 6.
113.	2004	<i>Vibrio vulnificus</i> Infections in Florida, Maria N. Donnelly, Florida DOH Epi Update, September 3.
114.	2004	Florida Student's Nursing Association 2004 Annual Convention Display, Kissimee, November 3-4.
115.	2004	Press release: DOH Reminds High Risk Individuals About Potential Risks Of Eating Raw Oysters, November 16.
116.	2004	Press release: DOH Issues Food Safety Guidelines for the Holidays, November 22.
117.	2004	Florida Department of Health Annual Food and Waterborne Illness Report
118.	2005	Summary of <i>Vibrio vulnificus</i> and High Risk Groups, Cordon Bleu Culinary School, Ft. Lauderdale, FL, January 6.
119.	2005	Epidemiology of <i>Vibrio vulnificus</i> , Food Safety Advisory Council – Tallahassee, January 19.
120.	2005	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, Grand Rounds, Teleconference, January 25.
121.	2005	Summary of <i>Vibrio vulnificus</i> and High Risk Groups, Community Health class, Tallahassee Community College – Tallahassee, February 2.
122.	2005	<i>Vibrio vulnificus</i> , Hepatitis Health (newsletter), Volume 2, Number 2, page 5, April.
123.	2005	Summary of <i>Vibrio vulnificus</i> and High Risk Groups, Food Microbiology class, University of Florida, Gainesville, March 14.
124.	2005	Summary of <i>Vibrio vulnificus</i> and High Risk Groups, University of Florida, County Extension Agent inservice, Teleconference, May 17.
125.	2005	Epidemiology of <i>Vibrio vulnificus</i> , Viral Hepatitis Council, Tampa, May 25.
126.	2005	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, University of Florida, County Extension Agent inservice, Teleconference, May 26.
127.	2005	Press release: DOH Reminds High Risk Individuals About Potential Risks Of Eating Raw Oysters, May 27.
128.	2005	<i>Vibrio vulnificus</i> in Florida, Epidemiology, Prevention and Health Education, Poster, Council of State and Territorial Epidemiologists Annual Meeting, Albuquerque, NM, June 6.
129.	2005	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, National Environmental Health Association Annual Education Conference, Providence, RI, June 29.
130.	2005	Florida <i>Vibrio vulnificus</i> display and poster at the Annual Meeting of the Florida Dietetic Association, Ft. Myers, July 11-12.
131.	2005	DACS and DOH are working with USEPA GMP, Florida Seagrant Program, ISSC, Gulf and South Atlantic States Fisheries Development Foundation, and FDA to provide a direct mailing to licensed physicians in AL, FL, GA, LA, and TX (>118,000) announcing the opportunity to participate in the free on line Vv CME course (letter with web link and Vv fact sheet).

	Year	Educational Activity
132.	2005	DACS and DOH are working with Florida SeaGrant Program and ISSC to provide advertisement in all publications of the <i>Florida Medical Association Quarterly</i> (circulation >17,000), the <i>Journal of the Louisiana State Medical Society</i> (circulation >7,000), and the <i>Texas Medicine</i> (circulation >34,000) beginning October 2005 through October 2008.
133.	2005	Press release: Florida Department Of Health Issues Food Safety Tips For Thanksgiving, November 22.
134.	2005	The Florida Department of Health Hepatitis Program sent out 353 <i>Vibrio vulnificus</i> brochures in English (with fact sheets on risks of people with liver disease) and 30 in Spanish to all inquiries of the Hepatitis Program (along with their regular information materials). 2005 calendar year.
135.	2005	Florida Department of Health Annual Food and Waterborne Illness Report
136.	2005/06	Worked with the oyster industry and the University of Florida to develop two State and FDA approved <i>Vibrio vulnificus</i> PHP processes (Nitrogen immersion and blast freezing). Working with the oyster industry and the University of Florida to gain state and FDA approval for another <i>Vibrio vulnificus</i> PHP process (heat shock followed by rapid cooling and freezing).
137.	2005/06	Continued law requirement more stringent than the NSSP for oysters to be under refrigeration at a licensed processor within 6 hours from time of harvest during the warmer months for <i>Vibrio vulnificus</i> .
138.	2005/06	Continued law requirement for Consumer Information Statement to be placed on restaurant menus or table tents and posted at retail establishments that sell raw oysters.
139.	2005/06	Ongoing: Continued membership in the ISSC <i>Vibrio vulnificus</i> Education Subcommittee.
140.	2005/06	Ongoing: Continued membership in the ISSC <i>Vibrio vulnificus</i> Subcommittee.
141.	2005/06	Ongoing: Continued membership in the ISSC <i>Vibrio</i> Management Committee.
142.	2005/06	Ongoing: Dr. Roberta Hammond, Florida Department of Health, continues to be the ISSC <i>Vibrio vulnificus</i> Education Coordinator.
143.	2006	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals at the Regional Environmental Epidemiology meeting, Port St. Lucie, February 22.
144.	2006	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, invited colloquium, University of Texas at El Paso, March 13.
145.	2006	<i>Vibrio vulnificus</i> , Hepatitis Health, Volume 2, Number 2, page 5 (newsletter). Florida Hepatitis and Liver Failure Control Program, April 2006.
146.	2006	Press release: DOH Reminds of the Risks Associated with Consuming Raw Oysters, May 2, 2006.
147.	2006	<i>Vibrio vulnificus</i> and Liver Disease. Links posted on the Florida Hepatitis and Liver Failure Control Program website, July 3, 2006
148.	2006	Florida <i>Vibrio vulnificus</i> display and poster at the Annual Meeting of the Florida Dietetic Association, Orlando, July 9-10.
149.	2006	Press release: Florida Department Of Health Issues Food Safety Tips For Thanksgiving, November 22.
150.	2006	Florida Department of Health Annual Food and Waterborne Illness Report
151.	2007	Press release: DOH Reminds Of The Risks Associated With Consuming Raw Oysters, April 26.
152.	2007	<i>Vibrio vulnificus</i> : Infection, Prevention and Treatment for Health Care Professionals, North Florida Infection Control Practitioners, Tallahassee, June 19.
153.	2007	An Overview of Foodborne Hepatitis A in Florida Along With a Special Concern for People With Liver Disease. The 2007 Florida Hepatitis Educational Conference, Orlando, June 29.

	<b>Year</b>	<b>Educational Activity</b>
154.	2007	Florida <i>Vibrio vulnificus</i> display and poster at the Annual Meeting of the Florida Dietetic Association, Marco Island, July 9-10.
155.	2007	<i>Vibrio vulnificus</i> : A Special Concern for People With Liver Disease, Hepatitis Support Group, Tallahassee, August 6.
156.	2007	The Florida Department of Health Hepatitis Program sent out Info Sheet Vv & Liver Disease: 2,264, Provider Fact Sheet: 260, Brochure: 578, Brochure (Spanish): 161 to all inquiries of the Hepatitis Program (along with their regular information materials). 2007 calendar year.
157.	2008	Press release: The Florida Department Of Health Reminds Floridians Of The Risks Associated With Raw Oyster Consumption, April 21, 2008.
158.	2008	<i>Vibrio vulnificus</i> Display at World Hepatitis Day, Tallahassee, May 19, 2008.
159.	2008	<i>Vibrio vulnificus</i> and the High Risk Patient: A Potentially Fatal Disease, FAFP (Florida Association for Food Protection) Connections (newsletter), Spring 2008 Issue (distribution 309).
160.	2008	<i>Vibrio vulnificus</i> Display (funded by GSAFF): Florida Dietetic Association 2008 Exhibition, Boca Raton, July 20-21.
161.	2008	<i>Vibrio vulnificus</i> Display (funded by GSAFF): Florida Academy of Physician Assistants 2008 Summer Symposium, Marco Island, July 30-August 1.
162.	2008	<i>Vibrio vulnificus</i> Display (funded by GSAFF): Florida Medical Association, Orlando, August 1-2, 2008.
163.	2008	<i>Vibrio vulnificus</i> Display (funded by GSAFF): Florida College of Emergency Physicians Symposium By The Sea 2008, Boca Raton, August 1-3.
164.	2008	<i>Vibrio vulnificus</i> Display (funded by GSAFF): Florida Environmental Health Association 60 <sup>th</sup> Annual Education Meeting & Trade Show, Palm Beach Gardens, August 11-15.
165.	2008	Radio spot in the Tampa Bay area on post-harvest processed (PHP) oysters: 105 Commercials aired on three Tampa area radio stations, nine rotating “Be Oyster Aware” banners on all three radio station websites, 770,000 Tampa area listeners reached.
166.	2008	PHP oyster blogs (funded by GSAFF): number of people that read the blogs is 670,309. State of Florida and Louisiana collaboration.
167.	2008	The Florida Department of Health Hepatitis Program sent out Info Sheet Vv & Liver Disease: 213, Provider Fact Sheet: 100, Brochure: 112 to all inquiries of the Hepatitis Program (along with their regular information materials). YTD October 3, 2008 calendar year. Note: Website and/or the order form for <i>Vibrio vulnificus</i> is now being given to healthcare providers, support groups, etc, and they're ordering direct
168.	2009	Foodborne pathogen review with WIC interns (including <i>Vibrio vulnificus</i> overview – not the one-hour training; 20 in attendance), Pasco County Health Department, New Port Richey, FL, March 13.
169.	2009	2008 Food and Waterborne Illness Outbreaks and Selected Case Studies, Central Florida Area (including brief overview of <i>Vibrio vulnificus</i> ).Florida Environmental Health Association Central District Education Workshop, Lakeland, FL, March 13, 2009
170.	2009	World Hepatitis Day, <i>Vibrio vulnificus</i> Display and handouts, Florida Capitol, Tallahassee, March 17.
171.	2009	Capstone Internship in Food Safety, Florida Agricultural and Mechanical University, Foodborne Illness Overview including overview of <i>Vibrio vulnificus</i> , 7 in attendance, Tallahassee, FL, March 31.

	<b>Year</b>	<b>Educational Activity</b>
172.	2009	2008 Food and Waterborne Illness Outbreaks and Selected Case Studies, Central Florida Area (including brief overview of <i>Vibrio vulnificus</i> ), Florida Department of Business and Professional Regulation, Division of Hotels and Restaurants, District IV Training, Orlando, Florida, May 4, 2009.
173.	2009	Grand Rounds: Reported Cases of Vibrio Illness in Florida, 1998-2007 (132 participants), Tallahassee, May 26.
174.	2009	Nutritional Epidemiology Graduate class (including brief overview of <i>Vibrio vulnificus</i> ; 35 attendees), University of North Florida, Jacksonville, FL, June 8.
175.	2009	Reported Cases of Vibrio Illness in Florida, 1998-2007 by Weis, Kristina E., Roberta M. Hammond, Richard Hutchinson and Carina Blackmore, poster displayed at the Council of State and Territorial Epidemiologists Annual Meeting, Buffalo, NY, June 9.
176.	2009	Food and Waterborne Infections (including brief overview of <i>Vibrio vulnificus</i> ), Florida Infectious Disease Society Symposium, Orlando, Florida, June 13, 2009
177.	2009	Food Safety Capstone Summer Teacher's Workshop, Florida Agricultural and Mechanical University, Foodborne Illness Overview including <i>Vibrio vulnificus</i> (including brief overview of <i>Vibrio vulnificus</i> ), 7 in attendance, Tallahassee, FL, June 29.
178.	2009	Foodborne Pathogen Review, pre-conference training at the Florida Environmental Health Association Annual Education Conference, including <i>Vibrio vulnificus</i> (including brief overview of <i>Vibrio vulnificus</i> ), 25 in attendance, Daytona Beach, August 13.
179.	2009	Sail and Power Squadron meeting (40 attendees). Handouts provided. Jacksonville, September 3.
180.	2009	Presentation of <i>Vibrio vulnificus</i> overview (not the one-hour training) and case investigation protocols, Palm Beach County Health Department, West Palm Beach, FL, September 17.
181.	2009	Agreed to Mentor and oversee a <i>Vibrio vulnificus</i> education and outreach project paper for a University of North Florida MPH team (3 students), Jacksonville, FL, September 28.
182.	2009	<i>Vibrio vulnificus</i> display and handouts at the Department of Agriculture and Consumer Services Safety and Health Fair, Tallahassee, FL, October 7.
183.	2009	Reported Cases of <i>Vibrio</i> Illness in Florida, 1998-2007 by Weis, Kristina E., Roberta M. Hammond, Richard Hutchinson and Carina Blackmore, article submitted to the Journal of Infections Diseases for publication (awaiting review and acceptance).
184.	2009	<i>Vibrio vulnificus</i> materials distributed by the DOH Hepatitis Program (total 587): 313 Fact Sheets, 19 Provider Guides, 154 Brochures (English), 101 Brochures (Spanish), to date (October 8).
185.	2009	<i>Vibrio vulnificus</i> . Hepatitis Health newsletter 6(7):3, October.
186.	2010	<i>Vibrio vulnificus</i> display and handouts at Hepatitis Awareness Day at the Florida Capitol, Tallahassee, FL, March 18.

Attachment 2 - US FDA *Vibrio vulnificus* Risk Calculator Output for Traditional Harvest.

month	water temperature (F)	Baseline air temperature during harvest (F)	Baseline: maximum time unrefrigerated (hr)	Baseline: maximum time to cooldown (hrs)	Baseline: # of servings	air (oyster) temperature during harvest (F)	maximum time unrefrigerated (hr)	maximum time to cooldown (hrs)	# of servings	mean log10 Vv/g at retail	risk (per 100,000 servings)	expected number of cases	# of cases for the baseline scenario
Jan	56.12	56.69	18	10	128,000	56.69	18	10	108,800	0.15	0.01	0.01	0.01
Feb	59.9	56.35	18	10	132,000	56.35	18	10	112,200	0.8	0.04	0.04	0.05
Mar	62.96	63.41	18	10	151,000	63.41	18	10	128,350	1.6	0.23	0.30	0.35
Apr	70.7	71.49	12	10	131,000	71.49	12	10	111,350	3	1.83	2.04	2.40
May	78.44	76.1	12	10	110,000	71.8	5	8	84,150	3.3	2.27	1.91	4.17
Jun	83.12	81.12	6	10	105,000	77.8	5	8	80,325	3.7	3.22	2.59	4.02
July	84.56	83.02	6	10	97,000	79.7	5	8	74,205	3.8	3.44	2.55	3.91
Aug	84.56	82.63	6	10	88,000	79.9	5	8	67,320	3.9	3.45	2.32	3.52
Sep	82.22	80.06	6	10	99,000	76.3	5	8	75,735	3.6	3.03	2.30	3.65
Oct	77.9	73.09	12	10	127,000	68.1	5	8	97,155	3.1	1.90	1.85	4.16
Nov	63.68	63.73	18	10	146,000	63.73	18	10	124,100	1.7	0.29	0.36	0.43
Dec	57.74	57.3	18	10	149,000	57.3	18	10	126,650	0.44	0.01	0.02	0.02
					1,463,000				1,190,340			<b>16.28</b>	26.70

  
**NEED 15 or 16**

Attachment 2 - (continued).

---

<b>Month</b>	<b>15% PHP</b>	<b>10% Reduced harvest</b>	<b>Air temp</b>	<b>Max time unrefrigerated</b>	<b>Max time to cooldown</b>
May	93500	84150	71.8	5	8
June	89250	80325	77.8	5	8
July	82450	74205	79.7	5	8
August	74800	67320	79.9	5	8
September	84150	75735	76.3	5	8
October	107950	97155	68.1	5	8

---

Attachment 3 - US FDA *Vibrio vulnificus* Risk Calculator Output for Complete On-Board Cooling Option.

month	water temperature (F)	Baseline air temperature during harvest (F)	Baseline: maximum time unrefrigerated (hr)	Baseline: maximum time to cooldown (hrs)	Baseline: # of servings	air (oyster) temperature during harvest (F)	maximum time unrefrigerated (hr)	maximum time to cooldown (hrs)	# of servings	mean log10 Vv/g at retail	risk (per 100,000 servings)	expected number of cases	# of cases for the baseline scenario	expected % reduction from baseline
Jan	56.12	56.69	18	10	128,000	56.69	18	10	108,800	0.15	0.01	0.01	0.01	15.0%
Feb	59.9	56.35	18	10	132,000	56.35	18	10	112,200	0.8	0.04	0.04	0.05	15.0%
Mar	62.96	63.41	18	10	151,000	63.41	18	10	128,350	1.6	0.23	0.30	0.35	15.0%
Apr	70.7	71.49	12	10	131,000	71.49	12	10	111,350	3	1.83	2.04	2.40	15.0%
May	78.44	76.1	12	10	110,000	76.99	1	8	84,150	3.2	2.14	1.80	4.17	56.7%
Jun	83.12	81.12	6	10	105,000	82.18	1	8	80,325	3.6	2.88	2.31	4.02	42.5%
July	84.56	83.02	6	10	97,000	84.01	1	8	74,205	3.6	3.04	2.25	3.91	42.4%
Aug	84.56	82.63	6	10	88,000	84.24	1	8	67,320	3.7	3.05	2.05	3.52	41.7%
Sep	82.22	80.06	6	10	99,000	80.75	1	8	75,735	3.5	2.75	2.08	3.65	43.0%
Oct	77.9	73.09	12	10	127,000	73.93	1	8	97,155	3.1	1.91	1.86	4.16	55.4%
Nov	63.68	63.73	18	10	146,000	63.73	18	10	124,100	1.7	0.29	0.36	0.43	15.0%
Dec	57.74	57.3	18	10	149,000	57.3	18	10	126,650	0.44	0.01	0.02	0.02	15.0%
					1,463,000				1,190,340			<b>15.12</b>	26.70	<b>43.3%</b>

**NEED 15 or 16**

Attachment 4 - US FDA *Vibrio vulnificus* Risk Calculator Output for Partial On-Board Cooling Option.

month	water temperature (F)	Baseline air temperature during harvest (F)	Baseline: maximum time unrefrigerated (hr)	Baseline: maximum time to cooldown (hrs)	Baseline: # of servings	air (oyster) temperature during harvest (F)	maximum time unrefrigerated (hr)	maximum time to cooldown (hrs)	# of servings	mean log10 Vv/g at retail	risk (per 100,000 servings)	expected number of cases	# of cases for the baseline scenario	expected % reduction from baseline
Jan	56.12	56.69	18	10	128,000	56.69	18	10	108,800	0.15	0.01	0.01	0.01	15.0%
Feb	59.9	56.35	18	10	132,000	56.35	18	10	112,200	0.8	0.04	0.04	0.05	15.0%
Mar	62.96	63.41	18	10	151,000	63.41	18	10	128,350	1.6	0.23	0.30	0.35	15.0%
Apr	70.7	71.49	12	10	131,000	71.49	12	10	111,350	3	1.83	2.04	2.40	15.0%
May	78.44	76.1	12	10	110,000	75.58	1	10	84,150	3.2	2.23	1.87	4.17	55.1%
Jun	83.12	81.12	6	10	105,000	81.05	1	10	80,325	3.6	3.03	2.44	4.02	39.4%
July	84.56	83.02	6	10	97,000	82.85	1	10	74,205	3.7	3.20	2.38	3.91	39.3%
Aug	84.56	82.63	6	10	88,000	83.14	1	10	67,320	3.7	3.22	2.17	3.52	38.4%
Sep	82.22	80.06	6	10	99,000	79.65	1	10	75,735	3.5	2.89	2.19	3.65	40.1%
Oct	77.9	73.09	12	10	127,000	72.43	1	10	97,155	3.1	1.96	1.90	4.16	54.3%
Nov	63.68	63.73	18	10	146,000	63.73	18	10	124,100	1.7	0.29	0.36	0.43	15.0%
Dec	57.74	57.3	18	10	149,000	57.3	18	10	126,650	0.44	0.01	0.02	0.02	15.0%
					1,463,000				1,190,340			15.71	26.70	41.2%

**NEED 15 or 16**

Attachment 5 - US FDA *Vibrio vulnificus* Risk Calculator Output for Rapid Cool Down Option.

month	water temperature (F)	Baseline air temperature during harvest (F)	Baseline: maximum time unrefrigerated (hr)	Baseline: maximum time to cooldown (hrs)	Baseline: # of servings	air (oyster) temperature during harvest (F)	Baseline: maximum time unrefrigerated (hr)	maximum time to cooldown (hrs)	# of servings	mean log10 Vv/g at retail	risk (per 100,000 servings)	expected number of cases	# of cases for the baseline scenario	expected % reduction from baseline
Jan	56.12	56.69	18	10	128,000	56.69	18	10	108,800	0.15	0.01	0.01	0.01	15.0%
Feb	59.9	56.35	18	10	132,000	56.35	18	10	112,200	0.8	0.04	0.04	0.05	15.0%
Mar	62.96	63.41	18	10	151,000	63.41	18	10	128,350	1.6	0.23	0.30	0.35	15.0%
Apr	70.7	71.49	12	10	131,000	71.49	12	10	111,350	3	1.83	2.04	2.40	15.0%
May	78.44	76.1	12	10	110,000	75.03	6	2	84,150	3.3	2.30	1.93	4.17	53.6%
Jun	83.12	81.12	6	10	105,000	80.65	6	2	80,325	3.7	3.16	2.54	4.02	36.8%
July	84.56	83.02	6	10	97,000	82.44	6	2	74,205	3.8	3.35	2.48	3.91	36.6%
Aug	84.56	82.63	6	10	88,000	82.74	6	2	67,320	3.8	3.37	2.27	3.52	35.6%
Sep	82.22	80.06	6	10	99,000	79.18	6	2	75,735	3.6	3.00	2.27	3.65	37.8%
Oct	77.9	73.09	12	10	127,000	71.71	6	2	97,155	3.1	2.00	1.94	4.16	53.4%
Nov	63.68	63.73	18	10	146,000	63.73	18	10	124,100	1.7	0.29	0.36	0.43	15.0%
Dec	57.74	57.3	18	10	149,000	57.3	18	10	126,650	0.44	0.01	0.02	0.02	15.0%
					1,463,000				1,190,340			<b>16.20</b>	26.70	<b>39.3%</b>

**NEED 15 or 16**

**THE FULL TEXT OF THE PROPOSED RULE AND THE FULL TEXT OF THE EXISTING RULE IS:**

5L-1.001 General Requirements and Intent.

(1) A shellfish processing plant certification is required to operate any shellfish processing facility.

(2) It is the intent of the Department to establish regulations and specifications to be known as the “Comprehensive Shellfish Control Code”, relating to sanitary practices for the catching, handling, relaying, depuration, packaging, preserving and storing of shellfish products.

(3) The Department, as a participant in the Interstate Shellfish Sanitation Conference, recognizes and endorses the following principles:

(a) Shellfish are a renewable, manageable natural and aquacultured resource of significant economic value to many coastal communities, and should be managed as carefully as are other natural resources such as forests, water, and agricultural lands.

(b) Shellfish culture and harvesting represents a beneficial use of water in the estuaries. This use should be recognized by local, state and federal agencies in planning and carrying out pollution prevention and abatement programs and in comprehensive planning for the use of these areas.

(c) The goals of the Interstate Shellfish Sanitation Conference are: 1. the continued safe use of this natural and aquacultured resource, and 2. active encouragement of water quality programs which will preserve all possible coastal areas for this beneficial use.

(4) The Department recognizes that the shellfish industry is subject to change as technological data becomes available; accordingly, it is the intent of the Department that the Comprehensive Shellfish Control Code be revised as necessary so that the technological data and industrial practices contained therein shall be consistent with good health and safety practices.

(5) The enforcement of the provisions of this code by the Department shall be coordinated with and be in conjunction with any and all other state, local and federal agencies exercising jurisdiction over the sanitary practices of the shellfish industry.

(6) Adoption of Federal Regulations and Standards – To the extent not inconsistent with the rules herein, the following are hereby adopted as rules under Section 597.020, F.S.:

(a) The following parts of Title 21, Code of Federal Regulations:

1. Part 7 – Enforcement Policy, revised as of April 1, 2000;
2. Part 101 – Food Labeling, revised as of April 1, 2000;
3. Part 109 – Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, revised as of April 1, 2000;
4. Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, revised as of April 1, 2000;
5. Part 123 – Fish and Fishery Products, revised as of April 1, 2000;
6. Part 161 – Fish and Shellfish, revised as of April 1, 2000;

7. Part 509 – Unavoidable Contaminants in Animal Food and Food Packaging Material, revised as of April 1, 2000.

(b) The Purpose, the Definitions, and Chapters 1 through 13, and 15 through 16 of the “Model Ordinance 2007 ~~1999~~” of the National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration 2007 ~~1999~~, except for:

1. Definition number (14)(d) Reshipper; and
2. Definition number (90) ~~(84)~~ Reshipper.

Interested persons may obtain copies of the pertinent sections of the Codes of Federal Regulations referenced in paragraph (a) above by contacting the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 [www.gpo.gov](http://www.gpo.gov). Copies of the Pertinent sections of the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Guide For The Control Of Molluscan Shellfish referenced in paragraph (b) above may be obtained by contacting the U.S. Government Printing Office or at the website <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm046353.htm>. Copies of all referenced documents are available for examination at the Florida Department of Agriculture and Consumer Services, Division of Aquaculture, 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301 [www.FloridaAquaculture.com](http://www.FloridaAquaculture.com).

*Specific Authority 597.020 FS. Law Implemented 597.020 FS. History–New 1-4-87, Amended 8-10-88, 7-9-89, 11-5-92, Formerly 16R-7.001, Amended 7-3-95, 2-6-97, 6-23-99, Formerly 62R-7.001, Amended 8-9-00, 5-29-02, 4-26-10.*

5L-1.007 Container Identification, Terminal Sale Date; Prohibitions.

(1) Shucked shellfish container – The packer’s or repacker’s shellfish processing plant certification license number preceded by the state abbreviation must be embossed, imprinted, lithographed, or otherwise permanently and legibly recorded on the external body of containers or on the lid if the lid becomes an integral part of the container during the sealing process (Example: FL-872-SP). Containers shall permanently indicate type of product, quantity, and name and address of packer, repacker, or distributor. Containers of fresh shellfish, with a capacity of less than 64 ounces, shall further clearly and permanently bear the terminal sale date, by the numerical month, day, and last digit of the year. Containers of fresh shellfish with a capacity of 64 ounces or more, shall bear the actual shucking date by numerical month, day, and last digit of the year, in that order (Example: 01015). Reusable bulk storage containers shall be identified with state of origin, harvest date, and shuck date. Containers of frozen or previously frozen shellfish shall further clearly and permanently bear the date of shucking by numerical month, day, and last digit of the year, in that order (Example: 02097). Previously frozen shucked shellfish shall also have the freeze date and the thaw date following the same format. The terminal sale date for previously frozen shucked shellfish will be calculated by adding the day of shucking plus amount of time under refrigeration if not frozen, and adding the days that the product has been held thawed. Repacked shellfish containers shall also bear

an appropriate code identifying the original packer. If oysters exceed the requirements time limit for refrigeration found in subsections 5L-1.008(5), (6), (7), (8) or (9), F.A.C., the shucked shellfish container may be identified with the language “FOR POST HARVEST PROCESSING COOKING ONLY”.

(2) Each commercial harvester or each certified shellfish dealer shall affix a durable, waterproof tag of minimal size – 2 5/8 by 5 1/4 inches – to each container of shellstock; for commercial harvesters this shall be done at each harvest location; for certified shellfish dealers this shall be done after final packing. In the case where a certified shellfish dealer is also the harvester, that dealer’s tag may also be used as the harvester’s tag.

(3) The commercial harvester’s tags shall contain legible waterproof indelible information arranged in the specific order as follows:

(a) The harvester’s saltwater product license number or aquaculture certificate number;

(b) The date of harvesting;

(c) The time of harvest (recorded as the time when the first shellfish is removed from the water for that specific bag or container);

(d) The time of refrigeration, if applicable;

(e) The identification of the harvest area using the four digit area number or name of the harvest area listed in subsection 5L-1.003(11), F.A.C., as well as the most precise identification within that area as practicable;

(f) Common name of shellfish and quantity of shellfish;

(g) The following statement will appear in bold capitalized type “THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.”

(h) The identification of the cooling option if used, including complete on-board cooling option (5L-1.008(7)), partial on-board cooling option (5L-1.008(8)), or rapid cooling option (5L-1.008(9)) for oysters harvested during the months of May through October.

(4) Bulk tagging is allowed for those aquaculturists operating with an aquaculture certificate. A bulk tag, containing the information required in paragraphs (3)(a)-(g) and (h), where applicable, along with the name of the certified shellfish dealer which the product is consigned to, shall be completed at each harvest location.

(5) Bulk tagging, by a certified shellfish dealer, while washing, packing, during depuration, wet storing, staging and intrastate transport of shellfish is permissible up to final packaging only when the lot container (i.e., pallet), contains shellfish which are harvested on the same day, from the same harvest area, and have the same intended use (i.e., for halfshell consumption, for shucking, or for further processing), and is tagged as follows:

(a) The statement “All Shellfish containers in this lot have the same date and area of harvest, as well as the same intended use”,

(b) Harvest date,

(c) Harvest area,

(d) Original Dealer/Shipper identification,

(e) Number of units in this lot container.

(f) The identification of the cooling option if used, including complete on-board cooling option (5L-1.008(7)), partial on-board cooling option (5L-1.008(8)), or rapid cooling option (5L-1.008(9)) for oysters harvested during the months of May through October.

(6) The dealer's tag shall contain legible, waterproof, indelible information arranged in the specific order as follows:

(a) The shellfish shipper, shucker-packer, repacker, depurator, or distributors name, address, processing plant certification number;

(b) The original shipper's certification number including the state abbreviation;

(c) The date of harvesting;

(d) The identification of the harvest area, and for Florida harvest areas the four digit code or name of the harvest area found in paragraph (3)(e) above;

(e) Common name of shellfish and quantity of shellfish; and

(f) The following statement will appear in bold capitalized type "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

(g) For oyster shellstock harvested from the Gulf of Mexico, the terminal sale date as a numeric date depicting month, day, and last digit of the year, not to exceed 14 days after the harvest date, or the statement "Sell Within 14 days of the Harvest Date".

(h) If shellstock exceeds the requirements ~~time limit for refrigeration found~~ in subsections 5L-1.008(5), ~~and (6), (7), (8) or (9)~~, F.A.C., the shellstock dealer tag shall be identified with the language "FOR SHUCKING ONLY BY A CERTIFIED DEALER" or "FOR POST HARVEST PROCESSING COOKING ONLY".

(i) For depuration processors, paragraphs (a), (d), (e), and (f) are required as well as the date of processing, and the depuration cycle number.

(j) For shellstock wet stored the following statement: "This product was wet stored on or at (Lease # or Facility certification number) from (date) to (date)".

(7) Containers of treated shellfish from depuration facilities shall be tagged in accordance with item (6) in addition to the lot number and date shellfish were released from the treatment plant.

(8) Shellfish identification, out-of-state – No shellfish from sources outside of Florida shall be brought into the state for purpose of resale or public distribution unless the product bears evidence of certification from the state or nation of origin and certification is based on requirements similar to those outlined in this chapter.

(9) In addition to the identification and labeling requirements of subsections (1) and (2), containers of fresh, frozen, previously frozen or repacked shellfish or containers of shellstock must indicate the state of origin of the shellfish, e.g., LA, MS, TX. For shellstock this requirement can be by paragraphs (6)(a) and (b) above.

(10) Shellstock and shucked shellfish containers shall be labeled with the following statement: "CONSUMER INFORMATION There is a risk associated with consuming raw shellfish. If you have chronic illness of the liver, stomach or blood or

have immune disorders, you are at greater risk of serious illness from raw shellfish and should eat shellfish fully cooked. If unsure of your risk, consult a physician.”

(11) It shall be unlawful for any person, firm, corporation, wholesale or retail dealer to sell or offer for sale any fresh shellfish after the terminal sale date has expired, or sell or offer for sale any fresh, frozen, or previously frozen shellfish not in compliance with any and all requirements of Chapter 5L-1, F.A.C.

(12) Whoever knowingly or willfully alters or damages in any manner, or loans or transfers to another person any certification license number or shellfish tags, or any person who uses the certification license or shellfish tags, other than the person to whom they were issued, shall be in violation of this section and shall be subject to certification license suspension or revocation in addition to any other penalty for violation of Chapter 5L-1, F.A.C.

*Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 5-21-87, 8-10-88, 7-9-89, 8-30-89, 5-6-93, 9-14-93, 8-21-94, Formerly 16R-7.010, Amended 9-1-95, 5-8-96, 2-6-97, 10-12-97, 2-12-98, 2-25-98, 7-1-98, 11-13-98, 12-28-98, 3-18-99, 7-1-99, Formerly 62R-7.010, Amended 6-19-00, 8-9-00, 10-14-01, 5-29-02, 8-17-04, 9-28-04, 7-28-08, 7-29-08, 4-26-10.*

#### 5L-1.008 Shellfish Handling.

(1) Wet storage shall be conducted upon execution of an agreement between a person, firm, or corporation possessing a shellfish processing plant certification license and the Department. Each agreement shall include the following provisions:

- (a) The coordinates in Latitude and Longitude where the facility is to be located.
- (b) A description of all facilities and equipment to be used to wet-store shellfish.
- (c) A listing of the species to be wet-stored.

(d) If the wet storage facility is to be located upon or in waters of the state, the facility shall be marked and lighted so as not to be a hazard to navigation.

(e) If the wet storage facility is to be located on or in waters of the state, and is to be a manned structure, it shall be equipped with a U.S. Coast Guard approved Type III marine sanitation device; this device shall be maintained in working order and be used by all personnel for disposal of bodily wastes.

(f) All solid wastes shall be removed from the wet storage facility daily and disposed of in a shore-based receptacle.

(g) No anti-fouling paints or finishes shall be used on any portion of the wet storage facility.

(h) No shellfish shall be removed from a wet storage facility when the shellfish harvesting area in which such shellfish are stored is closed pursuant to Rule 5L-1.003, F.A.C., or because of emergency conditions as defined by Rule 5L-1.002, F.A.C.

(i) Should maintenance of the wet storage facility require that the facility be relocated, written notification shall be provided to the Department, by certified mail, a minimum of 10 working days prior to such relocation. All shellfish shall be removed from the facility prior to relocation.

(j) If wet storage is to be practiced using a shore-based facility, the applicable provisions of Rules 5L-1.002, 5L-1.010, 5L-1.011, 5L-1.012, 5L-1.013, subsections 5L-1.015(2), (3), (4), (5), (6) and (7), and Rules 5L-1.017 and 5L-1.018, F.A.C., shall

apply. All shore-based facilities shall employ ultraviolet light treatment of all incoming and recirculated seawater. All water quality measurements required by Rule 5L-1.017, F.A.C., shall be documented and such data retained for inspection by the Department for a minimum of one year. Paragraphs 5L-1.008(1)(a), (b), (d), (e), (f), (h), and (i), F.A.C., shall not apply to a shore-based facility.

(k) The agreement shall be valid for no more than 1 year from the date it is signed by the Department.

(2) Boats and vehicles – Boats and vehicles used in harvesting or transporting shellfish shall be constructed, operated, and maintained, so as to protect the shellfish from contamination. Fuel tanks or other sources of contamination shall not be permitted to come into contact with shellfish. All boats used for commercial harvesting and handling shellfish shall be designed in such a way to prevent shellfish from coming in contact with any bilge water. No dogs or other animals or pets shall be allowed at any time on vessels or vehicles used to harvest or transport shellfish. No bodily wastes shall be discharged overboard from a harvest vessel. Shellstock harvested with commercial intent shall be protected by effective shading on harvest boats and vehicles to protect shellstock from exposure to sun, birds, and other adverse conditions. Shellfish shall be held under conditions which allows air circulation and promotes evaporative cooling.

(3) Boats engaged in harvesting or transporting shellfish shall have on board an approved Type III marine sanitation device, portable toilet or other sewage disposal receptacle. Portable toilets shall:

(a) Be constructed of high quality plastic that is durable, easy to clean and will not spill;

(b) Be used only for the purpose intended;

(c) Be secured while on board the vessel and located to prevent contamination of shellstock by spillage or leakage;

(d) Be emptied only into an appropriate sewage disposal system;

(e) Be cleaned before being returned to the boat; and

(f) Not be cleaned with equipment used for washing or processing food.

(4) Use of other receptacles for sewage disposal are approved if the receptacles are constructed of impervious, cleanable materials, have tight fitting lids, and meet the requirements of paragraphs 5L-1.008(3)(a)-(e), F.A.C.

(5) Throughout the year, it is harvester's responsibility that shellfish shall be harvested between sunrise and sunset as established by the U.S. Weather Service. During the months of November, December, January, February, and March, the harvester shall assure that shellfish shall be delivered to a certified shellfish dealer by 10:00 p.m. of the same day as harvest. During the months of April, May, and October, harvesters shall assure that ~~oysters or~~ clams shall be delivered to a certified shellfish dealer within twelve (12) hours of the time of harvest. During the month of April, the harvester shall assure that oysters shall be delivered to a certified shellfish dealer within twelve (12) hours of the time of harvest. During the months of May, June, and July, ~~August, and September~~, the harvesters shall assure that oysters shall be delivered to a certified shellfish dealer by 11:30 am unless authorized in a certified dealer HACCP plan for the complete on-board cooling option detailed in 5L-1.008(7) or authorized in a certified shellfish dealer HACCP plan for the partial on-board

cooling option detailed in 5L-1.008(8) or authorized in a certified shellfish dealer HACCP plan for the rapid cooling option detailed in 5L-1.008(9) within five (5) hours of the time of harvest. During the months of August, September, and October, the harvesters shall assure that oysters shall be delivered to a certified shellfish dealer by 12:00 pm unless authorized by the Department as detailed in 5L-1.008(7) for complete on-board cooling or authorized in a certified shellfish dealer HACCP plan for the partial on-board cooling option detailed in 5L-1.008(8) or authorized in a certified shellfish dealer HACCP plan for the rapid cooling option detailed in 5L-1.008(9) During the months of June, July, August, and September, the harvester shall assure that clams shall be delivered to a certified shellfish dealer within ten (10) hours of the time of harvest, or within the same day as harvest, whichever is earlier. All shellfish shall be delivered directly to a certified shellfish dealer possessing a shellfish processing plant certification license.

(6) Once received by a certified shellfish dealer, the shellstock lot shall be immediately processed and placed under temperature control and until sale to final consumer, the shellstock shall be maintained at an environmental temperature of 45° F or less and not be permitted to remain outside of temperature control for more than 2 hours cumulative at points of transfer within the processing plant such as loading docks or in the plant during processing except for the process described in paragraph 5L-1.013(3)(b), F.A.C. All certified shellfish dealers handling oysters must have a cooling system capable of reducing the internal temperature of shellstock oysters to 55 degrees F or less within 8-hours.

(7) Complete On-Board Cooling Option- On-board cooling equipment includes but is not limited to systems using ice, mechanical refrigeration or vacuum cooling. If a commercial oyster harvester is using on-board cooling, the maximum time oysters can remain outside the cooling system is 1 hour and the harvester must demonstrate to the department that the on-board cooling system is capable of reducing the internal temperature of oysters to 55 degrees F or less within 9 hours or less. Commercial harvesters using complete on-board cooling systems must deliver the oysters to a certified shellfish dealer no later than 4 pm. Certified shellfish dealers electing to purchase oysters from harvesters using complete on-board cooling systems must develop and demonstrate in their HACCP plan that the cooling rates on-board a vessel and in the certified shellfish dealer cooling system provide a safety level equivalent to product meeting subsection 5L-1.008(5), F.A.C. in order to be labeled in compliance with 5L-1.007(6), F.A.C. Certified shellfish dealers electing to purchase oysters from harvesters using such complete on-board cooling systems must list the harvester name, harvester license number, the maximum time oysters can be unrefrigerated on-board a vessel and the total number of hours required to reduce the internal temperature of oysters to 55 degrees F or less in their HACCP plan. Written approval must be received from the department prior to using such an on-board cooling system.

(8) Partial On-Board Cooling Option- Partial on-board cooling equipment includes but is not limited to systems using ice, mechanical refrigeration or vacuum cooling. If a commercial oyster harvester is using partial on-board cooling, the maximum time oysters can remain outside the cooling system is 1 hour and the harvester must demonstrate to the department that the on-board cooling system is

capable of reducing the internal temperature of oysters to 65 degrees F or less within 7 hours or less. Commercial harvesters using partial on-board cooling systems must deliver the oysters to a certified shellfish dealer no later than 3 pm. Certified shellfish dealers electing to purchase oysters from harvesters using on-board cooling systems must develop and demonstrate in their HACCP plan that the cooling rates on-board a vessel and in the certified shellfish dealer cooling system provide a safety level equivalent to product meeting subsection 5L-1.008(5), F.A.C. in order to be labeled in compliance with 5L-1.007(6), F.A.C. Certified shellfish dealers electing to purchase oysters from harvesters using such on-board cooling systems must list the harvester name, harvester license number, the maximum time oysters can be unrefrigerated on-board a vessel and the total number of hours required to reduce the internal temperature of oysters to 55 degrees F or less in their HACCP plan. Prior to implementing the HACCP plan the certified shellfish dealer must have written approval from the Department.

(9) Rapid Cooling Option- Rapid cooling equipment includes but is not limited to systems using ice, mechanical refrigeration or vacuum cooling. If a certified shellfish dealer elects to rapidly cool oysters, the maximum cool down time to 55 degrees F or less must not exceed 2 hours. Commercial oyster harvesters working with certified shellfish dealers using the rapid cooling option must deliver oysters to the certified shellfish dealer no later than 2 pm. The certified shellfish dealers must develop and demonstrate in their HACCP plan that the cooling rates in combination with extended harvest times assure a safety level equivalent to product meeting subsection 5L-1.008(5), F.A.C. in order to be labeled in compliance with 5L-1.007(6), F.A.C. Certified shellfish dealers electing this option, must list the harvester name, harvester license number, the maximum time oysters can be unrefrigerated on-board vessel and the total number of hours required to reduce the internal temperature of oysters to 55 degrees F or less in their HACCP plan. Prior to implementing the HACCP plan the certified shellfish dealer must have written approval from the Department.

(10) ~~(7)~~ Shellfish leaving a certified shellfish dealer must be transported in an enclosed, refrigerated conveyance with doors closed securely. The refrigeration unit must be capable of maintaining an ambient temperature of 45 degrees F or less at all times.

*Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 5-21-87, 8-10-88, 7-9-89, Formerly 16R-7.011, Amended 7-3-95, 2-6-97, 3-18-99, 6-23-99, Formerly 62R-7.011, Amended 8-9-00, 5-29-02, 7-29-08, 4-26-10.*

### 5L-1.013 Plant Operation.

(1) The plant shall operate in accordance with the HACCP plan designed and approved by the owner or corporate officers.

(2) Prior to acceptance of shellstock from a licensed harvester, certified shellfish dealer and/or certified aquaculturist, the certified shellfish dealer will ensure that shellstock are properly identified as specified in subsection 5L-1.007(3), F.A.C., are clean, wholesome, and alive.

(3) Upon acceptance of shellstock from a licensed harvester, certified aquaculturist or certified shellfish dealer, the receiving certified shellfish dealer shall

determine the appropriate use of the shellfish through examination of shellfish labeling as follows:

(a) Shellfish which fails to meet the requirements of subsection 5L-1.008(5), F.A.C., or is labeled in compliance with paragraph 5L-1.007(6)(h), F.A.C., shall only be used for shucking by a certified shellfish dealer, or labeled “For Post Harvest Processing ~~Cooking~~ Only”, or shall undergo an alternative post harvest processing method to assure a safety level equivalent to product meeting subsection 5L-1.008(5), F.A.C.

(b) Tempering, as an alternative process shall consist of those methods which have demonstrated through verification studies that the process renders hard clams which are as safe as hard clams meeting subsection 5L-1.008(5), F.A.C. Prior to initiating tempering a certified shellfish dealer shall have written approval from the Department. The certified shellfish dealer must provide the following:

1. A description of all facilities, equipment and methods to be used in the alternative process. This process must be included in the firm’s HACCP plan.

2. The source of hard clams and the maximum capacity of hard clams to undergo the process at any one time.

3. The process to be followed shall not exceed 16 hours total time between hard clam harvest and refrigeration at 45 degrees F or less. Product harvest, processing, tempering and food storage at 45 degrees F or less must be scheduled to occur as a continuous procedure.

4. Upon initiation, the tempering process must have temperature control of 68 degrees F or less and be maintained until hard clams are placed into refrigeration of 45 degrees F or less.

5. If facilities, equipment or methods change, the Department must be notified.

(c) Post Harvest Processing, including but not limited to such processes as frozen storage, hydrostatic high pressure, mild pasteurization, and irradiation, shall consist of those methods which have demonstrated through validation studies ~~that the process renders shellfish at least as safe as shellfish~~ meeting the requirements of Chapter XVI of the National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2007 ~~subsection 5L-1.008(5) and (6), F.A.C.~~ Prior to initiating post harvest processing, a certified shellfish dealer shall provide validation and obtain written approval from the Department.

(4) Shellfish shall be segregated by the certified shellfish dealer in accordance with its intended use as determined in paragraphs (3)(a) ~~– (c) and (b)~~ above and identified per subsection 5L-1.007(5) or (6), F.A.C.

(5) Unidentified, adulterated, unwholesome, dead, or contaminated shellstock shall be discarded.

(6) Shucking of shellfish – Shellfish shall be shucked in a manner such that they are not subjected to possible contamination. Only live shellfish shall be shucked.

(a) Shucked meats shall be delivered to the packing room within one hour.

(b) Shucked meats shall be thoroughly drained, cleaned as necessary, and packed promptly after delivery to the packing room. Packing operations shall be scheduled and conducted so as to chill all meats to an internal temperature of 45° F or less within two hours of delivery to the packing room. Shucked meats which are packed

into containers having a capacity of more than one gallon shall be pre-chilled to 45° F or less prior to packing.

(7) Shucked shellfish shall be held and transported at temperatures of 45° F or less.

(8) Ice shall be manufactured from potable water in a commercial machine which has been properly installed and maintained without connections to nonpotable water sources.

(9) Ice shall be stored so as not to come into contact with non-clean surfaces and is handled in such a manner that it will not be contaminated.

(10) Records – Complete, legible, and accurate dated records of purchase and sale of all shellfish shall be kept by all shellfish establishments operating in the state.

Records shall indicate:

- (a) From whom shellfish were purchased;
- (b) Areas from which shellstock were harvested;
- (c) State from which shucked shellfish were harvested;
- (d) Harvesting date;
- (e) The date of receipt by the processor;
- (f) Names and addresses of persons to whom shellfish were sold; and
- (g) Date sold.

(h) Records shall remain on file for not less than one year and shall be made available for inspection and copying by Department personnel during plant inspections.

(i) Production records shall be maintained for shucked meats which provide the amount of shellstock used, the harvest area, harvest date of the shellstock, and the amount of shucked meats produced.

(j) Production records shall be maintained for shellstock which provides for the amount of shellstock used, the harvest area, harvest date, harvest state, and the units of shellstock produces.

(k) Records covering purchases and sales of frozen or previously frozen shellfish shall be retained for at least two years or for a period of time that exceeds the shelf-life of the product.

(l) Records for shellfish lots having completed a depuration or wet storage treatment process shall include:

- 1. Counties from which shellfish were harvested;
- 2. Name or location of harvesting areas;
- 3. Relaying permit numbers, if applicable;
- 4. Date received in plant;
- 5. Date released from the plant;
- 6. Date and time of initiation of treatment;
- 7. Date and time of termination of treatment;
- 8. Ending UV unit meter readings;
- 9. Number of hours treated; and
- 10. All laboratory results as specified.

(11) Monitoring records of HACCP plan critical control points shall be maintained and reviewed at least weekly as specified in the firm's HACCP plan. Records shall be reviewed to ensure that the records are complete and to verify that

they document values that are within the critical limits. The review shall occur within one week of the day that the records are made. The reviewed records shall be signed and dated by an individual who is in a supervisory position in the firm and is knowledgeable of HACCP.

(12) Sanitation monitoring records shall be maintained for those conditions identified in subsection 5L-1.012(11), F.A.C., per the schedule of the activity, e.g. daily, weekly, monthly.

(13) Whenever a deviation from a critical limit occurs, a certified shellfish dealer shall take corrective action either by following a corrective action that is appropriate for the particular deviation, or by segregating and holding the affected product until a review can determine the acceptability of the affected product for distribution. Corrective actions include, when necessary, reconditioning, seizure, or destruction of affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. Corrective action also include, when necessary, correcting the cause of the deviation. All corrective actions shall be documented in writing.

(14) Responsibility – It shall be the duty and responsibility of each owner, manager, and operator of a shellfish plant to insure that all regulations pertaining thereto are strictly adhered to and that only safe, wholesome, unadulterated shellfish shall be produced. It shall be his or her duty and responsibility to see that the plant is properly supervised at all times and all shellfish can be identified, whether shellstock or shucked shellfish, to insure that they were harvested from approved growing waters and that they have been handled and processed in a sanitary manner.

*Specific Authority 597.020 FS. Law Implemented 597.020 FS. History–New 1-4-87, Amended 5-21-87, 8-10-88, Formerly 16R-7.016, Amended 7-3-95, 5-8-96, 2-6-97, 6-23-99, Formerly 62R-7.016, Amended 8-9-00, 5-29-02, 7-29-08, 4-26-10.*

NAME OF PERSON ORIGINATING PROPOSED RULE:

Sherman Wilhelm, Director, Division of Aquaculture

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE:

Charles Bronson, Commissioner, Department of Agriculture and Consumer Services

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 11, 2010

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW:

November 13, 2009.

## **Guidance for Implementation of Rule 5L-1.008 (5), (6), (7), (8) and (9), F.A.C. during 2010**

**April 1, 2010**

### **I. Who Needs to Conduct Time to Temperature Validation?**

Revisions to Rule 5L-1, F.A.C. incorporated in May, 2010 provide oyster processors in the State of Florida with two options to extend the hours available for oyster harvesters during May through October if on-board cooling options provided in the rule 5L-1.008(7) or (8), F.A.C, are used. An on-board cooling system must be validated and approved by the Florida Department of Agriculture and Consumer Services (DACs) with the results of an initial and final validation process to verify that the on-board cooling system has the capacity to meet time to temperature requirements specified in the rule.

Similarly, all oyster processors must provide the department with the results of a validation process to demonstrate that land based cooling systems have the required cooling capacity pursuant to section 5L-1-008(6), F.A.C. Additionally, any processor who chooses to purchase partially cooled oysters pursuant to Rule 5L-1.008(8), F.A.C., or chooses to rapidly cool oysters pursuant to Rule 5L-1.008(9), F.A.C. must provide DACs with the results of a validation process to document that the processors cooling system has the cooling capacity to meet time to temperature requirements specified in the rule.

The validation study procedures provided below are consistent with the guidance provided in Chapter IV.04 of the National Shellfish Sanitation Program (NSSP) Guidance Section (Attachment 7-A). Time to temperature validation of on-board cooling systems and cooling systems at the processing facility is the responsibility of the certified oyster processor who will handle the product.

## **II. What is Initial Validation and Final Validation?**

Because the revised rule will become effective prior to the most adverse water and air temperatures of the year, any cooling system used in May or June will need to complete an initial validation study between May 1, 2010 and June 30, 2010. Results of initial validations shall be provided to DACS upon completion of the validation test process. Final validations shall be conducted between July 1, 2010 and August 31, 2010 (during the most adverse temperature conditions expected during the year) and the results shall be provided to DACS by September 15, 2010. Once the cooling system has been validated under the most adverse conditions, the system will only need to be revalidated when a modification of the system occurs. Periodic HACCP verifications will confirm proper operation of the cooling system.

## **III. What is the Procedure to be used in Accomplishing the Time to Temperature Validation?**

**A. Processing Plant Refrigeration Systems.** Pursuant to Rule 5L-1.008(6), F.A.C., all refrigeration systems used to cool oysters by certified shellfish dealers must be capable of reducing the internal temperature of shellstock oysters to 55 degrees Fahrenheit or less within 8 hours following initial placement of product into the refrigeration system. Validation test results developed through the procedure below shall be forwarded to the dealer's FDACS inspector for evaluation and approval. In addition to the time-temperature results, the report shall include a physical description of the cooling system including physical dimensions, construction materials of the cooler, type of cooling gas (freon, ammonia, etc.), cooling capacity in BTU's, cooler settings (fan speed, thermostat, or any other power settings), temperature distribution within the cooler (warmest location), and maximum expected product load during May through October expressed in 60 pound bushels. If facilities, equipment, loading rates, or methods of cooling are modified, DACS must be notified and a new validation will be needed.

1. Initial validation testing for systems in operation during May or June of 2010 shall be conducted on two different processing days during May or June of 2010. For new systems to be put into operation after August 31, 2010, initial validation testing shall be conducted in September or October of 2010, with final validation to be conducted in July or August of 2011. All initial validations shall be conducted using the following procedure:

- The thermostat setting, fan setting, or other power setting at the time of initial loading shall be recorded and shall remain unchanged during the test. This setting should be the “normal” setting that will be used during operation of the facility.
- Cooler shall be loaded to the “maximum product load” expected for the months of May through October with oysters that have been harvested using traditional methods and transported without cooling or refrigeration.
- The test container shall be selected from a lot of oysters delivered to the dealer between 10:30 a.m. and 11:30 a.m. during May or June, and between 11:00 a.m. and 12:00 p.m. during September or October.
- The container selected as the test container should be the first container filled and tagged by the harvester on that day.
- The time of initial refrigeration shall be recorded at the time the test container of oysters is placed under refrigeration.
- The initial “zero hour” oyster temperature will be determined by inserting a calibrated thermometer into the test container or by measuring the internal temperature of three oysters in the test container.
- If individual product containers are normally stacked onto pallets, the test container shall be placed in a center location of the pallet, and the pallet containing the test container should be placed in the warmest location of the cooler as previously defined.
- If using a calibrated hand held thermometer, oyster temperature at the center of the test container shall be checked on an hourly basis for ten hours and the time that the oyster temperature reaches 55 degrees Fahrenheit or less will be recorded as the time of final cool down.
- If using a continuous time-temperature recorder (TTR), the temperature probe shall be placed in the center of the test container and allowed to monitor oyster temperature for 10 hours, and the time that the oyster temperature reaches 55 degrees Fahrenheit or less will be recorded as the time of final cool down.
- The total time required for cooling oysters to 55 degrees Fahrenheit will be calculated by subtracting the time of initial refrigeration from the time of final cool down.
- The time and temperature data resulting from each test shall be compiled in a table and submitted to DACS as part of the validation report.
- (optional) The data generated by the validation test rendering the longest cool down time shall be plotted on a graph with the Y axis being oyster

“Temperature” in degrees Fahrenheit, and the X axis being “Time” in hours. The line graph resulting will be the established temperature curve for that specific refrigeration system during the initial validation.

2. Final validation testing shall be conducted on three separate days in July or August using the procedure established in A.1. (above).

**B. On-board Cooling Systems.** Pursuant to Rule 5L-1.008(7) and 5L-1.008(8), F.A.C., complete on-board cooling systems must be capable of cooling oysters to 55 degrees Fahrenheit or less within 9 hours, and partial on-board cooling systems must be capable of cooling oysters to 65 degrees Fahrenheit or less within 7 hours following initial placement of the product into the cooling system. Validation test results developed through the procedure below shall be forwarded to the dealer’s DACS inspector for evaluation and approval. In addition to the test results, the report should include a physical description of the cooling system including physical dimensions, construction materials, type of cooling media, cooling capacity in BTU’s (mechanical refrigeration only), and maximum expected product load during May through October expressed in 60 pound bushels. If ice is used as a cooling media, the report should include the total volume or weight of ice used, and the ratio of ice to product. If facilities, equipment or methods of cooling change, DACS must be notified and a new or revised validation will be needed.

1. Initial validation testing for systems in operation during May or June of 2010 shall be conducted on two different processing days during May or June of 2010. For new systems to be put into operation after August 31, 2010, initial validation testing shall be conducted in September or October of 2010, with final validation to be conducted in July or August of 2011. All initial validations shall be conducted using the following procedure:

- If using mechanical refrigeration, the thermostat setting, fan setting, or other power setting at the time of initial loading shall be recorded and shall remain unchanged during the test. The setting used should be the “normal” setting that will be used during operation of the cooling system.
- The first bag or container placed into the cooling system shall be identified as the test container, and the time and initial oyster temperature shall be measured and recorded.

- The cooling system shall be loaded to the “normally” expected capacity for the months of May through October with oysters that have been harvested using traditional methods.
- If using a hand held thermometer, the temperature of an oyster in the center of the test container shall be measured after 7 hours of operation to determine if the system meets the requirements of a partial on-board cooling system, and after 9 hours of operation to determine if the system meets the requirements of a complete on-board cooling system. The total time required for cooling oysters to 65 degrees Fahrenheit and 55 degrees Fahrenheit shall be calculated and recorded.
- If using a continuous time-temperature recorder (TTR), the temperature probe shall be placed in the center of the test container and allowed to monitor oyster temperature for 9 hours. The times that the oyster temperature reaches 65 degrees Fahrenheit or less and 55 degrees Fahrenheit or less shall be recorded and used to calculate the total time required for partial and complete cooling.
- The time and temperature data resulting from each test shall be compiled in a table and submitted to DACS as part of the validation report.

2. Final validation testing will be conducted on three separate days in July or August using the procedure established in B.1. (above).

**C. Rapid Cooling Systems.** Pursuant to Rule 5L-1.008(9), F.A.C., rapid cooling systems must be capable of cooling oysters to 55 degrees Fahrenheit within 2 hours following initial placement of product into the refrigeration system. Validation test results developed through the procedure below shall be forwarded to the dealer’s DACS inspector for evaluation and approval. In addition to the test results, the report should include a physical description of the cooling system including physical dimensions, construction materials, type of cooling media, and cooling capacity in BTU’s (mechanical refrigeration only). If ice is used as a cooling media, the report should include the total volume or weight of ice used, and the ratio of ice to product. If facilities, equipment or methods of cooling are modified, the DACS must be notified and a new or revised validation will be needed.

1. Initial validation testing for systems in operation during May or June of 2010 shall be conducted on two different processing days during May or June of 2010. For new systems to be put into operation after August 31, 2010, initial validation testing shall be conducted in September or October of 2010, with final validation to

be conducted in July or August of 2011. All initial validations shall be conducted using the following procedure:

- If using mechanical refrigeration, the thermostat setting, fan setting, or other power setting at the time of initial loading shall be recorded and shall remain unchanged during the test. This setting should be the “normal” setting that will be used during operation of the facility.
- Rapid cooling system shall be loaded to the “normally” expected capacity with oysters that have been harvested using traditional methods and transported without cooling or refrigeration.
- The test container or test oysters should be selected from a lot of oysters delivered to the dealer between 1:00 p.m. and 2:00 p.m.
- The container selected as the test container should be the first container filled and tagged by the harvester on that day.
- The time of initial cooling shall be recorded at the time the test container or test oysters are placed into the cooling system.
- The initial “zero hour” oyster temperature will be determined by inserting a calibrated thermometer in the center of the container touching the oyster shells, or if no container is used, averaging the meat temperatures of three oysters in the test lots.
- If using a hand held thermometer, oyster temperature shall be measured and recorded every 10 minutes for 2 hours (more frequently if the cooling process is shorter than 2 hours) and the time that the oyster temperature reaches 55 degrees Fahrenheit or less will be recorded as the time of final cool down.
- If using a continuous time-temperature recorder (TTR), oyster temperature will be measured for 2 hours and the time that the oyster temperature reaches 55 degrees Fahrenheit or less will be recorded as the time of final cool down.
- The total time for cooling oysters to 55 degrees Fahrenheit will be calculated by subtracting the time of initial refrigeration from the time of final cool down.
- The time and temperature data resulting from each test shall be compiled in a table and submitted to DACS as part of the validation report.
- (Optional) The data generated by the test rendering the longest cool down time may also be plotted on a graph with the Y axis being oyster “Temperature” in degrees Fahrenheit and the X axis being “Time” in hours. The line graph resulting will be the established temperature curve for that specific cooling system during the initial validation.

2. Final validation testing shall be conducted on three separate days in July or August using the procedures established in C.1. (above).

#### **IV. Will Certified Dealers Need to Modify Their HACCP Plan?**

Any oyster processor who handles oysters pursuant to Rule 5L-1.008(5), (6), (7), (8), or (9), F.A.C. must have a revised HACCP Plan that identifies new critical control points, requires appropriate monitoring and record keeping, and specifies the corrective actions to be taken when product does not meet the time to temperature requirements specified in Rule 5L-1.008, F.A.C. The dealer's HACCP plan will also define the verification process necessary to assure the cooling system used is consistently achieving the required cool down times. Any oyster processor who handles oysters pursuant to Rule 5L-1.008(7),(8), or (9), must also include in their HACCP Plan the names and license numbers of all harvesters that will be delivering oysters to the dealer under the options provided for complete, partial, or rapid cooling. DACS will provide assistance to certified oyster processors in making the necessary updates to their current HACCP plans.

**Proposal No. 09-233**

**ISSC 2009 Summary of Actions Page 366**

**Proposal Subject:** Validation and Verification for Process Studies for Time and Temperature Requirements Related to *Vibrio* Management Plan Controls

**Specific NSSP Guide Reference:**

NSSP Guide Section IV. Guidance Documents  
Chapter IV. Naturally Occurring Pathogens  
.04 Post Harvest Processing (PHP) Validation/Verification Guidance for  
*Vibrio vulnificus* and *Vibrio parahaemolyticus*

**Text of Proposal/Requested Action**

- A. Process Validation
- B. Equipment Validation
- C. Initial Load Testing
- D. Verification

**9. Time to temperature controls shall be evaluated using standard protocols for measuring temperatures in shellfish. A protocol shall include the number of samples, when and where samples will be collected and temperatures measured. The protocols will include procedures that can be included in harvester and dealer record keeping to document compliance with time to temperature requirements.**

**Public Health Significance:**

Implementation of the *Vibrio vulnificus* Management Plans will require establishing times to refrigeration and times to cool down to 55 degrees. It is important that standardized measuring methods be agreed upon in order to be sure that time to temperature requirements are being accomplished by harvesters and dealers. Additionally, agreed upon validation and verification activities will lead to greater uniformity in implementing *Vibrio* controls.

**Cost Information (if available):**

None available

**Action by 2009 Task Force II:**

Recommended approval of substituted language for Proposal 09-233.  
.05 Guidance for Demonstrating the Effectiveness of Time to Temperature Reduction Criteria for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Time-to-Temperature Protocol

- (1) Identify the target time/temperature requirements for the specific cooling system/unit.
- (2) Demonstrate that each cooling method and unit is capable of meeting the target time/temperature by conducting a process study under worst case conditions for that unit. The following parameters should be considered and utilized in conducting the process study:
  - a. maximum load for the cooling unit
  - b. initial product temperature (studies have demonstrated that measurement of the external temperature and the internal meat temperatures are comparable and either can be used)
  - c. location of hot spot(s)

d. thermostat setting(s)

e. cooling method(s) used

f. method of loading the cooling unit

(3) Include a description of the process; a record of the process study conducted; and monitoring records in a HACCP Plan.

(4) The protocol should be applied at the first point of refrigeration

**Action by 2009 General Assembly**

Adopted recommendation of 2009 Task Force II on Proposal 09-223.e

## Shellstock Oysters (Traditional Harvest)

**Product Description:** Shellstock Oysters

**Fishery Product Market Name:** Oysters (*Crassostrea virginica*)

**Source of Fishery Product:** Wild caught in the Gulf of Mexico

**Methods of Packaging, Distribution and Storage:** Shellstock oysters stored and distributed refrigerated at 45°F

**Intended Use and Consumer:** By the general public – to be eaten raw or fully cooked

### **Description of Process:**

#### **Receive oysters**

- During the months of November through March shellstock oysters must be delivered to the certified dealer by 10:00 PM.
- During the month of April shellstock oysters must be delivered to the certified dealer within 12 hours.
- During the months of May, June and July shellstock oysters must be delivered to the certified dealer by 11:30 AM.
- During the months of August, September and October shellstock oysters must be delivered to the certified dealer by 12:00 PM.
- Oyster shellstock is received from harvester via vessel or by land transport: Product is weighed and bagged into 60 lb sacks (bushels). Harvest tags are checked for correct harvest area and time of harvest. Oysters must be received no later than the times specified above during the applicable month(s). Receiving record with applicable information is completed at time of receipt. Oysters received directly from harvesters which fail to meet the above specified delivery times must be labeled “for shucking only” or “for PHP only”

**Shellstock refrigerated storage** – Bags of shellstock are then immediately placed into refrigerated storage at an ambient temperature of 45° F or less until needed for processing. Refrigerated storage must be validated (***see addendum #1***) as capable of reducing the internal temperature of the shellstock oysters to 55° F or less within 8 hours.

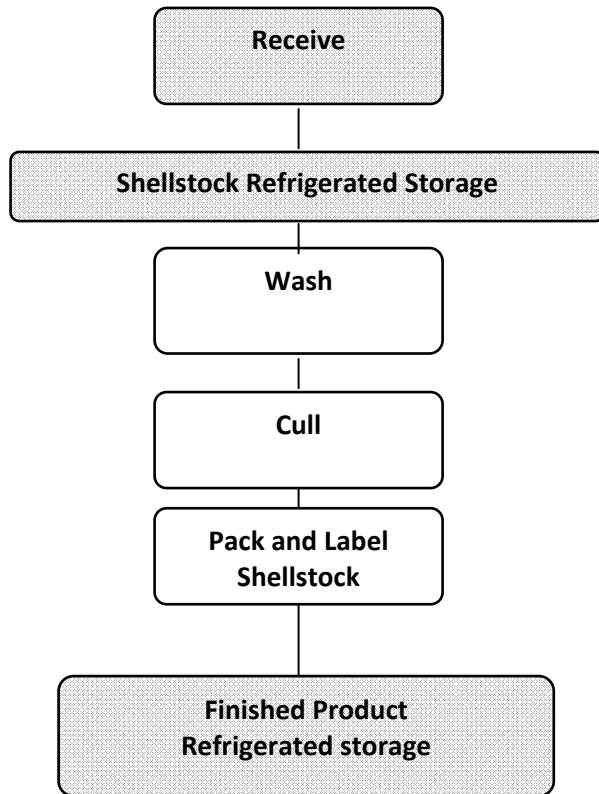
**Wash** – On an as needed basis, shellstock is removed from storage and placed into conveyers where it is washed (*approximate time*).

**Cull** – Washed oysters are culled and graded.

**Shellstock Pack and Label** – Oyster shellstock is packed according to customer specification and labeled.

**Finished product refrigerated storage** – Boxes of oyster shellstock or iced containers of shucked oysters are stored under refrigeration at 45° F or less until they are distributed.

**Shellstock Oysters  
(Traditional Harvest)  
Process Flow Diagram**  
*Shaded step are Critical Control Points*



**(Traditional Harvest)**

<b>Hazard Analysis Worksheet for Shellstock Oysters (Page 1 of 3)</b>					
<b>Firm Name:</b>			<b>Product Description:</b> Shellstock Oysters – <i>C. virginica</i>		
<b>Firm Location:</b>			<b>Method of Storage &amp; Distribution:</b> Refrigerated (45° F)		
			<b>Intended Use &amp; Consumer:</b> To be consumed raw by the general public.		
(1) <b>Processing Step</b>	(2) List all potential <b>biological, chemical, and physical food safety hazards</b> that could be associated with this product and process.	(3) Is the potential food safety hazard <b>significant</b> (introduced, enhanced or eliminated) at this step? <b>(Yes or No)</b>	(4) <b>Justify the decision</b> that you made in column 3	(5) What <b>control measure(s)</b> can be applied to prevent this significant hazard?	(6) Is this step a <b>Critical Control Point?</b> <b>(Yes or No)</b>
Receive	Pathogens from the harvest area	Yes	Oysters are filter feeders and are likely to accumulate biological contaminants from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester.	<b>Yes</b>
	Natural Toxins	Yes	Oysters are filter feeders and are likely to accumulate toxins from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester.	<b>Yes</b>
	Environmental Chemicals	Yes	Oysters are filter feeders and are likely to accumulate chemical contaminants from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester.	<b>Yes</b>
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester.  Receive oyster shellstock no later than the times specified for the applicable month(s).	<b>Yes</b>
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**(Traditional Harvest)**

**Hazard Analysis Worksheet for Shellstock Oysters (Page 2 of 3)**

<b>Firm Name:</b>					
<b>Firm Location:</b>					
Shellstock Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45° F/7° C to reduce the internal temperature of shellstock oysters to 55° F/13° C or less within 8 hours. <b>(see validation study and annual verification on file).</b>	<b>Yes</b>
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Wash	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Cull	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**(Traditional Harvest)**

**Hazard Analysis Worksheet for Shellstock Oysters (Page 3 of 3)**

<b>Firm Name:</b>					
<b>Firm Location:</b>					
Pack and Label	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Finished Product Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45°F/7°C	<b>Yes</b>
	Food Allergens / Additives (undeclared)	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

### HACCP Plan for Shellstock Oysters – Traditional Harvest (Page 1 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Receive	<p>Pathogens from the harvest area</p> <p>Natural toxins</p> <p>Chemical contaminants</p>	<p>Shellfish must be harvested from open status waters</p> <p>Harvester must have a valid license</p> <p>Harvest tag that identifies the date, time and place of harvest, type, and quantity of shellfish</p>	<p>Harvest area and status</p> <p>Harvester's license number</p> <p>Harvest tag information</p>	<p>Obtain from local FDACS SEAS office by phone, fax, e-mail or internet &amp; document harvest area closures and re-openings for applicable harvest areas.</p> <p>Visual check</p> <p>Visual check</p>	<p>Each closure &amp; re-opening</p> <p>Each delivery</p> <p>Each delivery</p>	<p>Area Supervisor</p>	<p>If harvest tag is in-complete, harvester does not have a valid license or harvest waters are closed, then reject oysters</p>	<p>Records review within one week of activity</p> <p>Annual check that harvest license has been renewed for approved harvesters.</p>	<p>Harvest Area Status Record/Closure Record</p> <p>Harvest/Purchase Record</p>

**HACCP Plan for Shellstock Oysters – Traditional Harvest (Page 2 of 3)**

Receive	Pathogen growth – temperature abuse	<p>During the months of <u>November through March</u> shellstock oysters must be received by 10:00 PM.</p> <p>During the month of <u>April</u> shellstock oysters must be received within 12 hours.</p> <p>During the months of <u>May, June and July</u> shellstock oysters must be received by 11:30 AM.</p> <p>During the months of <u>August, September and October</u> shellstock oysters must be received by 12:00 PM.</p>	Time of receipt	Visual and clock	Each delivery	Area Supervisor	If the receiving time specified for the applicable month is not met, then affected product must be segregated and labeled with the language “FOR SHUCKING ONLY BY A CERTIFIED DEALER’ or “FOR POST HARVEST PROCESSING ONLY.”	Records review within one week of activity	Shellfish Receiving Record  Corrective Action Record
Shellstock Refrigerated Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler Temperature	Visual Check	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	<p>Records review within one week of activity</p> <p>Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer</p> <p>Annual verification of shellstock cooler validation</p>	<p>Cooler Temperature Record</p> <p>Cooler Thermometer Calibration/ Accuracy Verification Record</p> <p>Cooler Validation Record with Annual Verification (<i>addendum #1</i>) Corrective Action Record</p>

### HACCP Plan for Shellstock Oysters – Traditional Harvest (Page 3 of 3)

Finished Product Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler temperature	Visual check of cooler thermometer	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	Records review within one week of activity  Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer	Cooler Temperature Record  Cooler Thermometer Calibration/ Accuracy Verification Record  Cooler Validation Record with Annual Verification ( <i>addendum #1</i> ) Corrective Action Record
<b>FIRM NAME :</b> _____					<b>Product Description:</b> <i>Shellstock Oysters</i> <b>Method of Storage &amp; Distribution:</b> <i>Refrigerated (45° F)</i> <b>Intended Use and Consumer:</b> <i>By the general public – to be eaten raw or fully cooked</i>				
<b>FIRM ADDRESS :</b> _____									
<b>Signature:</b> _____					<b>Date Signed:</b> _____				

**\*CORRECTIVE ACTION** SHELLSTOCK: If cooler temperature is > 45 °F, check meat temperature. If shellstock meat temperature is between 45°F - 50 °F, the product will be placed in a working cooler at 45 °F or <. If cooler temperature is > 45°F and shellstock meat temperature is > 50 °F the product will be will be placed in a working cooler at 45 °F or < , isolated and evaluated to insure the product is safe. **Revised: 3/15/2010**

## **Shellstock Oysters (Complete On-board Cooling Option)**

**Product Description:** Shellstock Oysters

**Fishery Product Market Name:** Oysters (*Crassostrea virginica*)

**Source of Fishery Product:** Wild caught in the Gulf of Mexico

**Methods of Packaging, Distribution and Storage:** Shellstock oysters stored and distributed refrigerated at 45°F

**Intended Use and Consumer:** By the general public – to be eaten raw or fully cooked

**Description of Process:**

**Harvest Vessel's On-board Cooling System** – The on-board cooling system must be validated and FDACS (Department) approved as capable of reducing the internal temperature of the oysters to 55° F or less within 9 hours. Shellstock oysters must be placed under on-board cooling within 1 hour of harvest (***see validation of on-board cooling system and written Department approval, addendum #1***).

**Receive oysters** – Live oyster shellstock are harvested from open status waters and properly tagged by a licensed harvester listed in certified processor's current HACCP plan (***see addendum #2***). On-board cooling system is checked for ambient temperature or presence of cooling media. Product is weighed and bagged into 60 lb sacks (bushels). Harvest tags are checked for harvest date, harvest area, time of harvest, time of on-board refrigeration and identification of correct on-board cooling option. Oysters must be received no later than 4:00 PM. Receiving record with applicable information is completed at time of receipt.

**Shellstock refrigerated storage** – Bags of shellstock are then immediately placed into refrigerated storage at an ambient temperature of 45° F or less until needed for processing. Refrigerated storage must be validated (***see addendum #3***) as capable of reducing the internal temperature of the shellstock oysters to 55° F or less within 8 hours.

**Wash** – On an as needed basis, shellstock is removed from storage and placed into conveyers where it is washed (*approximate time*).

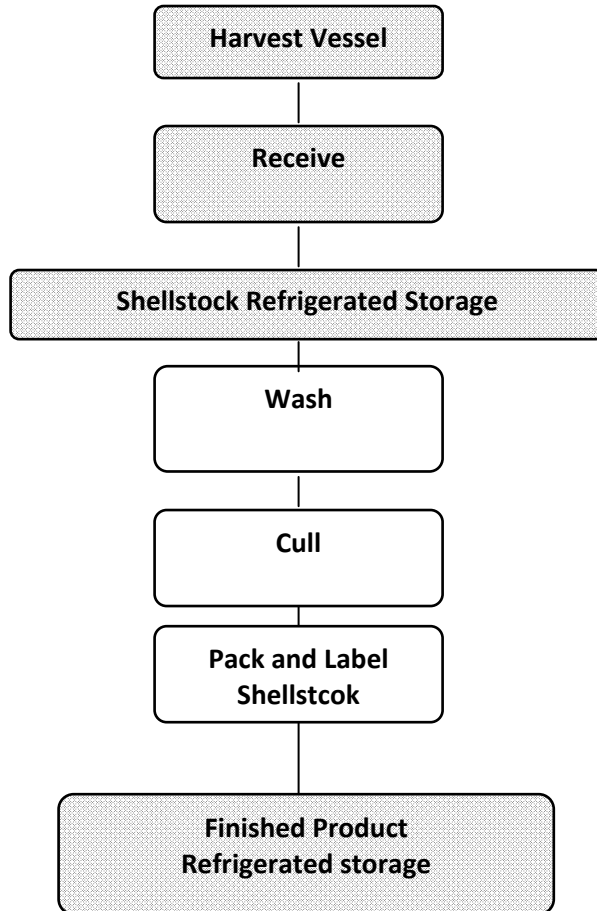
**Cull** – Washed oysters are culled, graded and distributed to the shucking stations (*approximate time*).

**Shellstock Pack and Label** – Oyster shellstock is packed according to customer specification and labeled.

**Finished product refrigerated storage** – Boxes of oyster shellstock or iced containers of shucked oysters are stored under refrigeration at 45° F or less until they are distributed.

**Shellstock Oysters  
(Complete On-board Cooling Option)  
Process Flow Diagram**

*Shaded step are Critical Control Points*



## Shellstock Oysters (Complete On-board Cooling Option)

### Hazard Analysis Worksheet (Page 1 of 3)

<b>Firm Name:</b>	<b>Product Description:</b> Shellstock Oysters – <i>C. virginica</i>
<b>Firm Location:</b>	<b>Method of Storage &amp; Distribution:</b> Refrigerated (45° F)
	<b>Intended Use &amp; Consumer:</b> To be consumed raw by the general public.

(1) Processing Step	(2) List all potential <b>biological, chemical, and physical food safety hazards</b> that could be associated with this product and process.	(3) Is the potential food safety hazard <b>significant</b> (introduced, enhanced or eliminated) at this step? <b>(Yes or No)</b>	(4) <b>Justify the decision</b> that you made in column 3	(5) What <b>control measure(s)</b> can be applied to prevent this significant hazard?	(6) Is this step a <b>Critical Control Point?</b> <b>(Yes or No)</b>
Receive	Pathogens from the harvest area	Yes	Oysters are filter feeders and are likely to accumulate biological contaminants from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Natural Toxins	Yes	Oysters are filter feeders and are likely to accumulate toxins from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Environmental Chemicals	Yes	Oysters are filter feeders and are likely to accumulate chemical contaminants from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan with a validated and Department approved on-board cooling system capable of reducing the internal temperature of oysters to 55 °F or less within 9 hours or less.  Receive oyster shellstock by 4:00 PM.	Yes
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**Shellstock Oysters**  
**(Complete On-board Cooling Option)**  
**Hazard Analysis Worksheet (Page 2 of 3)**

<b>Firm Name:</b>					
<b>Firm Location:</b>					
Shellstock Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45° F/7° C to reduce the internal temperature of shellstock oysters to 55° F/13° or less within 8 hours.	<b>Yes</b>
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Wash	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Cull	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**Shellstock Oysters  
(Complete On-board Cooling Option)  
Hazard Analysis Worksheet (Page 3 of 3)**

<b>Firm Name:</b>						
<b>Firm Location:</b>						
Pack and Label	Pathogens from the harvest area	No	Controlled at receive step			
	Natural Toxins	No	Controlled at receive step			
	Environmental Chemicals	No	Controlled at receive step			
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step			
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used			
	Metal Inclusion	No	Not likely to occur at this process step			
Finished Product Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step			
	Natural Toxins	No	Controlled at receive step			
	Environmental Chemicals	No	Controlled at receive step			
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45°F/7°C		<b>Yes</b>
	Food Allergens / Additives (undeclared)	No	Molluscan shellfish are not a major food allergen and no food additives are used			
	Metal Inclusion	No	Not likely to occur at this process step			

## HACCP Plan for Shellstock Oysters - Complete On-board Cooling Option (Page 1 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Receiving	<p>Pathogens from the harvest area</p> <p>Natural toxins</p> <p>Chemical contaminants</p>	<p>Shellfish must be harvested from open status waters</p> <p>Harvester must have a valid license and be listed in addendum to certified processor's current HACCP plan</p> <p>All containers must have a Complete On-board Cooling Option harvest tag with consignee and that identifies the date, time and place of harvest, time of on-board refrigeration, harvester license number, type, and quantity of shellfish</p>	<p>Harvest area and status</p> <p>Harvester's license number per addendum</p> <p>Harvest tag information</p>	<p>Obtain from local FDACS SEAS office by phone, fax, e-mail or internet &amp; document harvest area closures and re-openings for applicable harvest areas.</p> <p>Visual check</p> <p>Visual check</p>	<p>Each closure &amp; re-opening</p> <p>Each delivery</p> <p>Each delivery</p>	Area Supervisor	<p>If harvest tag is in-complete, harvester is not listed in addendum or harvest waters are closed, then reject oysters</p>	<p>Records review within one week of activity</p> <p>Annual check that harvest license has been renewed for approved harvesters.</p>	<p>Harvest Area Status Record/Closure Record</p> <p>Harvest/ Purchase Record</p> <p>(Addendum #'s 1 &amp; 2)</p>

## HACCP Plan for Shellstock Oysters - Complete On-board Cooling Option (Page 2 of 3)

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving	Pathogen growth – temperature abuse	Harvest vessel must have a validated and Department approved on-board cooling system capable of reducing the internal temperature of oysters to 55 °F/13 ° C or less within 9 hours.  Must be received by 4:00 PM	Listed in addendum #1 , on file	Visual check	Each delivery	Area Supervisor	Reject product if harvester is not listed in addendum or does not have a validated on-board cooling system.  If the 4:00 PM receiving time for complete on-board cooling option is not met, then affected product must be segregated and labeled with the language “FOR SHUCKING ONLYBY A CERTIFIED DEALER’ or “FOR POST HARVEST PROCESSING ONLY.”	Records review within one week of activity	Shellfish Receiving Record  (Addendum #'s 1 & 2)  Corrective Action Record
			Time of receipt	Visual and clock	Each delivery				

## HACCP Plan for Shellstock Oysters - Complete On-board Cooling Option (Page 3 of 3)

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Shellstock Refrigerated Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler Temperature	Visual Check	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	Records review within one week of activity  Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer  Annual verification of cooler validation	Cooler Temperature Record  Cooler Thermometer Calibration/ Accuracy Verification Record  Cooler validation records ( <i>addendum #3</i> ) Corrective Action Record
Finished Product Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler temperature	Visual check of cooler thermometer	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	Records review within one week of activity  Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer	Cooler Temperature Record  Cooler Thermometer Calibration/ Accuracy Verification Record  Corrective Action Record

<b>FIRM NAME :</b>  <b>FIRM ADDRESS :</b>  <b>Signature:</b> _____	<b>Product Description:</b> <i>Shellstock Oysters</i> <b>Method of Storage &amp; Distribution:</b> <i>Refrigerated (45° F)</i> <b>Intended Use and Consumer:</b> <i>By the general public – to be eaten raw or fully cooked</i>  <b>Date Signed:</b> _____
--	--

\***CORRECTIVE ACTION** SHELLSTOCK: If cooler temperature is > 45 °F, check meat temperature. If shellstock meat temperature is between 45°F - 50 °F, the product will be placed in a working cooler at 45 °F or <. If cooler temperature is > 45°F and shellstock meat temperature is > 50 °F the product will be will be placed in a working cooler at 45 °F or < , isolated and evaluated to insure the product is safe. **Revised: 3/15/2010**

## **Shellstock Oysters (Partial On-board Cooling Option)**

**Product Description:** Shellstock Oysters

**Fishery Product Market Name:** Oysters (*Crassostrea virginica*)

**Source of Fishery Product:** Wild caught in the Gulf of Mexico

**Methods of Packaging, Distribution and Storage:** Shellstock oysters stored and distributed refrigerated at 45°F

**Intended Use and Consumer:** By the general public – to be eaten raw or fully cooked

**Description of Process:**

**Harvest Vessel's On-board Cooling System** – The on-board cooling system must be validated and FDACS (Department) approved as capable of reducing the internal temperature of the oysters to 65° F or less within 7 hours. Shellstock oysters must be placed under on-board cooling within 1 hour of harvest (***see validation of on-board cooling system and written Department approval, addendum #1***).

**Receive oysters** – Live oyster shellstock are harvested from open status waters and properly tagged by a licensed harvester listed in certified processor's current HACCP plan (***see addendum #2***). On-board cooling system is checked for ambient temperature or presence of cooling media. Product is weighed and bagged into 60 lb sacks (bushels). Harvest tags are checked for harvest date, harvest area, time of harvest, time of on-board refrigeration and identification of correct on-board cooling option. Oysters must be received no later than 3:00 PM. Receiving record with applicable information is completed at time of receipt.

**Shellstock refrigerated storage** – Bags of shellstock are then immediately placed into refrigerated storage at an ambient temperature of 45° F or less until needed for processing. Refrigerated storage must be validated (***see addendum #3***) as capable of reducing the internal temperature of the shellstock oysters to 55° F or less within 8 hours.

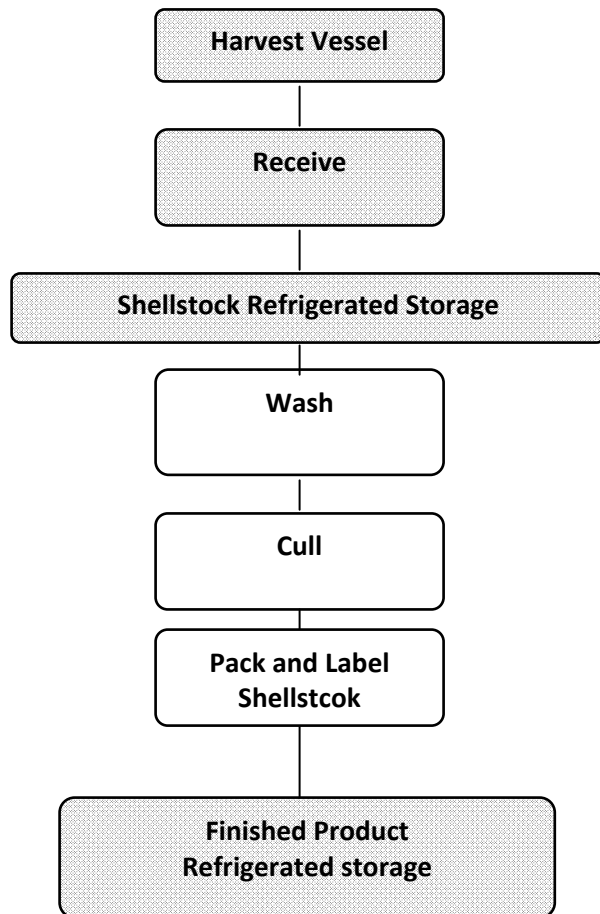
**Wash** – On an as needed basis, shellstock is removed from storage and placed into conveyers where it is washed (*approximate time*).

**Cull** – Washed oysters are culled, graded and distributed to the shucking stations (*approximate time*).

**Shellstock Pack and Label** – Oyster shellstock is packed according to customer specification and labeled.

**Finished product refrigerated storage** – Boxes of oyster shellstock or iced containers of shucked oysters are stored under refrigeration at 45° F or less until they are distributed.

**Shellstock Oysters**  
**(Partial On-board Cooling Option)**  
**Process Flow Diagram**  
*Shaded step are Critical Control Points*



## Shellstock Oysters (Partial On-board Cooling Option)

### Hazard Analysis Worksheet (Page 1 of 3)

<b>Firm Name:</b>	<b>Product Description:</b> Shellstock Oysters – <i>C. virginica</i>
<b>Firm Location:</b>	<b>Method of Storage &amp; Distribution:</b> Refrigerated (45° F)
	<b>Intended Use &amp; Consumer:</b> To be consumed raw by the general public.

(1) Processing Step	(2) List all potential <b>biological, chemical, and physical food safety hazards</b> that could be associated with this product and process.	(3) Is the potential food safety hazard <b>significant</b> (introduced, enhanced or eliminated) at this step? <b>(Yes or No)</b>	(4) <b>Justify the decision</b> that you made in column 3	(5) What <b>control measure(s)</b> can be applied to prevent this significant hazard?	(6) Is this step a <b>Critical Control Point?</b> <b>(Yes or No)</b>
Receive	Pathogens from the harvest area	Yes	Oysters are filter feeders and are likely to accumulate biological contaminants from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Natural Toxins	Yes	Oysters are filter feeders and are likely to accumulate toxins from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Environmental Chemicals	Yes	Oysters are filter feeders and are likely to accumulate chemical contaminants from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan with a validated and Department approved on-board cooling system capable of reducing the internal temperature of oysters to 65 °F/18 °C or less within 7 hours or less.  Receive oyster shellstock by 3:00 PM.	Yes
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**Shellstock Oysters  
(Partial On-board Cooling Option)  
Hazard Analysis Worksheet (Page 2 of 3)**

<b>Firm Name:</b>					
<b>Firm Location:</b>					
Shellstock Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45° F/7° C to reduce the internal temperature of shellstock oysters to 55° F/13° C or less within 8 hours.	<b>Yes</b>
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Wash	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Cull	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**Shellstock Oysters**  
**(Partial On-board Cooling Option)**  
**Hazard Analysis Worksheet (Page 3 of 3)**

<b>Firm Name:</b>					
<b>Firm Location:</b>					
Pack and Label	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Finished Product Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45°F/7°C	<b>Yes</b>
	Food Allergens / Additives (undeclared)	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

## HACCP Plan for Shellstock Oysters - Partial On-board Cooling Option (Page 1 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Receiving	<p>Pathogens from the harvest area</p> <p>Natural toxins</p> <p>Chemical contaminants</p>	<p>Shellfish must be harvested from open status waters</p> <p>Harvester must have a valid license and be listed in addendum to certified processor's current HACCP plan</p> <p>All containers must have a Partial On-board Cooling Option harvest tag with consignee and that identifies the date, time and place of harvest, time of on-board refrigeration, harvester license number, type, and quantity of shellfish</p>	<p>Harvest area and status</p> <p>Harvester's license number per addendum</p> <p>Harvest tag information</p>	<p>Obtain from local FDACS SEAS office by phone, fax, e-mail or internet &amp; document harvest area closures and re-openings for applicable harvest areas.</p> <p>Visual check</p> <p>Visual check</p>	<p>Each closure &amp; re-opening</p> <p>Each delivery</p> <p>Each delivery</p>	<p>Area Supervisor</p>	<p>If harvest tag is incomplete, harvester is not listed in addendum or harvest waters are closed, then reject oysters</p>	<p>Records review within one week of activity</p> <p>Annual check that harvest license has been renewed for approved harvesters.</p>	<p>Harvest Area Status Record/Closure Record</p> <p>Harvest/ Purchase Record <i>(Addendum #'s 1 &amp; 2)</i></p> <p>Corrective Action Record</p>

## HACCP Plan for Shellstock Oysters - Partial On-board Cooling Option (Page 2 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Receive	Pathogen growth – temperature abuse	Harvest vessel must have a validated and Department approved on-board cooling system capable of reducing the internal temperature of oysters to 65 °F/18 ° C or less within 7 hours.  Must be received by 3:00 PM	Listed in addendum #1 , on file  Time of receipt	Visual check  Visual and clock	Each delivery  Each delivery	Area Supervisor	Reject product if harvester is not listed in addendum or does not have a validated on-board cooling system.  If the 3:00 PM receiving time for partial on-board cooling option is not met, then affected product must be segregated and labeled with the language “FOR SHUCKING ONLYBY A CERTIFIED DEALER’ or “FOR POST HARVEST PROCESSING ONLY.”	Records review within one week of activity	Shellfish Receiving Record  (Addendum #'s 1 & 2)  Corrective Action Record

## HACCP Plan for Shellstock Oysters - Partial On-board Cooling Option (Page 3 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Shellstock Refrigerated Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler Temperature	Visual Check	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	Records review within one week of activity  Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer  Annual verification of cooler validation	Cooler Temperature Record  Cooler Thermometer Calibration/ Accuracy Verification Record  Cooler validation records ( <i>addendum #3</i> ) Corrective Action Record
Finished Product Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler temperature	Visual check of cooler thermometer	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	Records review within one week of activity  Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer	Cooler Temperature Record  Cooler Thermometer Calibration/ Accuracy Verification Record  Corrective Action Record

<b>FIRM NAME :</b>  <b>FIRM ADDRESS :</b>  <b>Signature:</b> _____	<b>Product Description:</b> <i>Shellstock Oysters</i> <b>Method of Storage &amp; Distribution:</b> <i>Refrigerated (45° F)</i> <b>Intended Use and Consumer:</b> <i>By the general public – to be eaten raw or fully cooked</i>  <b>Date Signed:</b> _____
--	--

**\*CORRECTIVE ACTION:** SHELLSTOCK: If cooler temperature is > 45 °F, check meat temperature. If shellstock meat temperature is between 45°F - 50 °F, the product will be placed in a working cooler at 45 °F or <. If cooler temperature is > 45°F and shellstock meat temperature is > 50 °F the product will be placed in a working cooler at 45 °F or < , isolated and evaluated to insure the product is safe. **Revised: 3/15/2010**

## **Shellstock Oysters (Rapid Cooling Option)**

**Product Description:** Shellstock Oysters

**Fishery Product Market Name:** Oysters (*Crassostrea virginica*)

**Source of Fishery Product:** Wild caught in the Gulf of Mexico

**Methods of Packaging, Distribution and Storage:** Shellstock oysters stored and distributed refrigerated at 45°F

**Intended Use and Consumer:** By the general public – to be eaten raw or fully cooked

**Description of Process:**

**Harvester** – Must be a licensed harvester listed in certified processor's current HACCP plan (*see addendum #1*)

**Receive oysters** – Live oyster shellstock are harvested from open status waters and properly tagged by a licensed harvester listed in certified processor's current HACCP plan (*see addendum #1*). Product is weighed and bagged into 60 lb sacks (bushels). Harvest tags are checked for cooling option, harvest date, harvest area and time of harvest. Oysters must be received no later than 2:00 PM. Receiving record with applicable information is completed at time of receipt.

**Rapid Cooling** – The maximum time oysters can remain outside the cooling system is from sunrise (as established by the U.S. Weather Service) until 2:00 PM. The maximum cool down to 55° F or less must not exceed 2 hours (*may be validated – see addendum #2*)

(insert description of rapid cooling option here)

**Shellstock refrigerated storage** – Bags of shellstock are then immediately placed into refrigerated storage at an ambient temperature of 45° F or less until needed for processing. Refrigerated storage must be validated (*see addendum #3*) as capable of reducing the internal temperature of the shellstock oysters to 55° F or less within 8 hours.

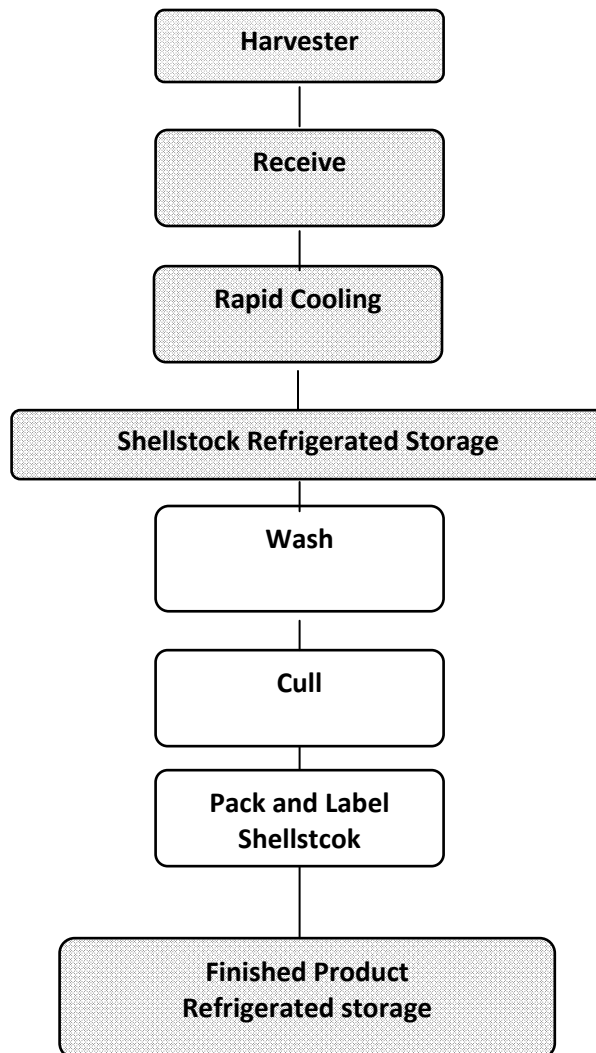
**Wash** – On an as needed basis, shellstock is removed from storage and placed into conveyers where it is washed (*approximate time*).

**Cull** – Washed oysters are culled, graded and distributed to the shucking stations (*approximate time*).

**Shellstock Pack and Label** – Oyster shellstock is packed according to customer specification and labeled.

**Finished product refrigerated storage** – Boxes of oyster shellstock or iced containers of shucked oysters are stored under refrigeration at 45° F or less until they are distributed.

**Shellstock Oysters  
(Rapid Cooling Option)  
Process Flow Diagram**  
*Shaded step are Critical Control Points*



## Shellstock Oysters (Rapid Cooling Option)

### Hazard Analysis Worksheet (Page 1 of 3)

<b>Firm Name:</b>	<b>Product Description:</b> Shellstock Oysters – <i>C. virginica</i>
<b>Firm Location:</b>	<b>Method of Storage &amp; Distribution:</b> Refrigerated (45° F)
	<b>Intended Use &amp; Consumer:</b> To be consumed raw by the general public.

(1) Processing Step	(2) List all potential <b>biological, chemical, and physical food safety hazards</b> that could be associated with this product and process.	(3) Is the potential food safety hazard <b>significant</b> (introduced, enhanced or eliminated) at this step? <b>(Yes or No)</b>	(4) <b>Justify the decision</b> that you made in column 3	(5) What <b>control measure(s)</b> can be applied to prevent this significant hazard?	(6) Is this step a <b>Critical Control Point?</b> <b>(Yes or No)</b>
Receive	Pathogens from the harvest area	Yes	Oysters are filter feeders and are likely to accumulate biological contaminants from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Natural Toxins	Yes	Oysters are filter feeders and are likely to accumulate toxins from the growing area	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Environmental Chemicals	Yes	Oysters are filter feeders and are likely to accumulate chemical contaminants from the growing area	Only receive oyster shellstock harvested from open status and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.	Yes
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Only receive oyster shellstock harvested from open status waters and properly tagged by a licensed harvester listed in addendum to certified processor's current HACCP plan.  Receive oyster shellstock by 2:00 PM.	Yes
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**Shellstock Oysters  
(Rapid Cooling Option)  
Hazard Analysis Worksheet (Page 2 of 3)**

<b>Firm Name:</b>					
<b>Firm Location:</b>					
Rapid Cooling	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if oyster shellstock are not rapidly cooled	Reduce the internal temperature of oyster shellstock to 55° F/13° C or less within 2 hours.	Yes
	Food Allergens / Additives	No	<b>Molluscan shellfish are not a major food allergen and no food additives are used</b>		
	Metal Inclusion	No	Not likely to occur at this process step		
Shellstock Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45° F/7° C	Yes
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Wash	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

**Shellstock Oysters  
(Rapid Cooling Option)  
Hazard Analysis Worksheet (Page 3 of 3)**

**Firm Name:**

**Firm Location:**

Cull	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Pack and Label	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Food Allergens / Additives	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		
Finished Product Refrigerated Storage	Pathogens from the harvest area	No	Controlled at receive step		
	Natural Toxins	No	Controlled at receive step		
	Environmental Chemicals	No	Controlled at receive step		
	Pathogen growth – temperature abuse	Yes	Levels of pathogens are likely to increase if temperature abused	Maintain cooler temperature below 45°F/7°C	<b>Yes</b>
	Food Allergens / Additives (undeclared)	No	Molluscan shellfish are not a major food allergen and no food additives are used		
	Metal Inclusion	No	Not likely to occur at this process step		

### HACCP Plan for Shellstock Shipper - Rapid Cooling Option (Page 1 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Receiving	<p>Pathogens from the harvest area</p> <p>Natural toxins</p> <p>Chemical contaminants</p>	<p>Shellfish must be harvested from open status waters</p> <p>Harvester must have a valid license and be listed in addendum to certified processor's current HACCP plan</p> <p>All containers must have a Rapid Cooling Option harvest tag with consignee and that identifies the date, time and place of harvest, harvester license number, type, and quantity of shellfish</p>	<p>Harvest area and status</p> <p>Harvester's license number per addendum # 1</p> <p>Harvest tag information</p>	<p>Obtain from local FDACS SEAS office by phone, fax, e-mail or internet &amp; document harvest area closures and re-openings for applicable harvest areas.</p> <p>Visual check</p> <p>Visual check</p>	<p>Each closure &amp; re-opening</p> <p>Each delivery</p> <p>Each delivery</p>	Area Supervisor	<p>If harvest tag is incomplete, harvester is not listed in addendum or harvest waters are closed, then reject oysters</p>	<p>Records review within one week of activity</p> <p>Annual check that harvest license has been renewed for approved harvesters.</p>	<p>Harvest Area Status Record/Closure Record</p> <p>Harvest/Purchase Record <i>(Addendum # 1)</i></p> <p>Corrective Action Record</p>

### HACCP Plan for Shellstock Shipper - Rapid Cooling Option (Page 2 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
.Receive	Pathogen growth – temperature abuse	Must be received by 2:00 PM	Time of receipt	Visual and clock	Each delivery	Area Supervisor	Reject product if harvester is not listed in addendum  If the 2:00 PM receiving time for the Rapid cooling option is not met, then affected product must be segregated and labeled with the language “FOR SHUCKING ONLY BY A CERTIFIED DEALER’ or “FOR POST HARVEST PROCESSING ONLY.”	Records review within one week of activity	Shellfish Receiving Record  Corrective Action Record
Rapid Cooling	Pathogen growth	The maximum cool down to 55° F or less must not exceed 2 hours.	Time of receipt, start time, finish time and cooling system environmental temperature at start and finish.	Visual and clock	Each delivery	Area Supervisor	If the 2:00 PM receiving time for the Rapid cooling option is not met, then affected product must be segregated and labeled with the language “FOR SHUCKING ONLY BY A CERTIFIED DEALER’ or “FOR POST HARVEST PROCESSING ONLY.”	Records review within one week of activity	Rapid Cool down Record  Cooling System Validation Record (Addendum #2)  Corrective Action Record  Cooler Thermometer Calibration/ Accuracy Verification Record

### HACCP Plan for Shellstock Shipper - Rapid Cooling Option (Page 3 of 3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Control Measure	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			
Shellstock Refrigerated Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler Temperature	Visual Check	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	Records review within one week of activity  Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer  Annual verification of cooler validation	Cooler Temperature Record  Cooler Thermometer Calibration/ Accuracy Verification Record  Cooler Validation Record ( <i>Addendum #3</i> ) Corrective Action Record
Finished Product Storage	Pathogen growth – temperature abuse	Cooler temperature 45° F/7° C or below	Cooler temperature	Visual check of cooler thermometer	Twice daily during working hours when product is in cooler and once daily on non operating days when product is in cooler	Area Supervisor	Follow corrective actions listed below*	Records review within one week of activity  Monthly calibration of cooler temperature monitoring device, or verification with calibrated thermometer	Cooler Temperature Record  Cooler Thermometer Calibration/ Accuracy Verification Record  Corrective Action Record

<b>FIRM NAME :</b>  <b>FIRM ADDRESS :</b>  <b>Signature:</b> _____	<b>Product Description:</b> <i>Shellstock Oysters</i> <b>Method of Storage &amp; Distribution:</b> <i>Refrigerated (45° F)</i> <b>Intended Use and Consumer:</b> <i>By the general public – to be eaten raw or fully cooked</i>  <b>Date Signed:</b> _____
--	--

\***CORRECTIVE ACTION** SHELLSTOCK: If cooler temperature is > 45 °F, check meat temperature. If shellstock meat temperature is between 45°F - 50 °F, the product will be placed in a working cooler at 45 °F or <. If cooler temperature is > 45°F and shellstock meat temperature is > 50 °F the product will be placed in a working cooler at 45 °F or <, isolated and evaluated to insure the product is safe. **Revised: 3/15/2010**