

NOTICE OF PROPOSED RULE

FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

DIVISION OF AQUACULTURE

RULE TITLE:	RULE NO:
General Requirements and Intent	5L-1.001
Container Identification, Terminal Sale Date; Prohibitions	5L-1.007
Shellfish Handling	5L-1.008
Plant Operation	5L-1.013

PURPOSE AND EFFECT: These amendments propose to further protect the health of oyster consumers and ensure the State of Florida meets the requirements of the National Shellfish Sanitation Program (NSSP) as it relates to *Vibrio vulnificus*. The proposed rule amendments significantly impact commercial harvesting and processing of oysters.

SUMMARY: These proposed amendments apply to commercial oyster harvesting and processing in Florida in order to protect the health of oyster consumers and to provide continued limited access to oyster resources during warmer months. Specifically, restrictions on oyster harvesting times are proposed from May through October. Additionally, these proposed amendments describe additional container identification requirements. To compensate for these restrictions, three different oyster cooling options for harvesters and processors are proposed by these amendments, provided written approval from the Department is obtained prior to implementing the certified dealer's HACCP plan. Furthermore, the Model Ordinance 2007 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 is adopted, thereby replacing the 1999 version adopted previously.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: The agency has determined that this rule will have an impact on small businesses. A SERC has been prepared by the agency. A written comment received by an oysterman association representing approximately 20 fishermen and 3 wholesalers indicated the proposed rule amendments may reduce their landings by a minimum of 50%. The agency could not estimate the cost to any state or local government entities. No good faith written proposals were received for a lower cost regulatory alternative to the proposed rule which would have substantially accomplished the objectives and were supported by a majority of workshop participants. Any person who wishes to provide information regarding the statement of estimated regulatory costs or to provide a proposal for a lower cost regulatory alternative must do so in

writing within 21 days of this notice.

RULEMAKING AUTHORITY: 597.020 FS.

LAW IMPLEMENTED: 597.020 FS.

HEARINGS WILL BE HELD AT THE TIME, DATE AND PLACES SHOWN BELOW:

TIME AND DATE: 4:00 pm EST, March 19, 2010

PLACE: Franklin County Courthouse Annex, Commission Meeting Room, 34 Forbes St., Apalachicola, FL 32320

TIME AND DATE: 4:00 pm EST, March 22, 2010

PLACE: South Ponte Vedra Civic Association, 2724 South Ponte Vedra Blvd, Ponte Vedra Beach, FL 32082

TIME AND DATE: 5:00 pm EST, March 23, 2010

PLACE: Senator George G. Kirkpatrick Marine Lab, 11350 SW 153rd Court, Cedar Key, FL 32625

If accommodation for a disability is needed to participate in this activity, please notify Chris Brooks, Division of Aquaculture, at (850) 488-4033 at least seven days before the meeting.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Chris Brooks, Division of Aquaculture, 1203 Governor's Square Boulevard, 5th Floor, Tallahassee, Florida 32301, Phone: (850) 488-4033

THE FULL TEXT OF THE PROPOSED RULE IS:

5L-1.001 General Requirements and Intent.

(1) – (5) No change.

(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) No change.

(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. 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.

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,

_____.

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) No change.

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

(a) – (b) No change.

(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) – (g) No change.

(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) – (e) No change.

(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) – (g) No change.

(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) – (j) No change.

(7) – (12) No change.

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, _____.

5L-1.008 Shellfish Handling.

(1) – (4) No change.

(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) (↔) 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, _____.

5L-1.013 Plant Operation.

(1)- (2) No change.

(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) No change

(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) – (14) No change.

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, _____.

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