

## FISCAL IMPACTS OF PROPOSED RULE 15A NCAC 03K .0110

### IMPLEMENTING NATIONAL SHELLFISH SANITATION PROGRAM HARVESTER AND DEALER REQUIREMENTS

#### Marine Fisheries Commission (MFC)

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**Impact Summary:** State Government: Yes  
Local Government: No  
Private Impact: Yes  
Substantial Impact: No

**Authority:** G.S. 113-134 (Rules); G.S. 113-182 (Regulation of Fishing and Fisheries); G.S. 113-201 (Legislative Findings and Declaration of Policy; Authority of Marine Fisheries Commission); G.S. 113-221.1 (Proclamations; Emergency Review); G.S. 143B-289.52 (Marine Fisheries Commission-Powers and Duties)

**Necessity:** This rule is proposed for adoption to establish authority for the Fisheries Director to implement requirements of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, Section II (Model Ordinance) via proclamation. The Model Ordinance establishes minimum requirements that states must meet for the sanitary control of molluscan shellfish.

#### Summary:

Proclamation authority is needed to allow timely implementation and enforcement of National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Section II (Model Ordinance) that frequently changes on an annual basis. The Division of Marine Fisheries (DMF) also needs to be able to enforce existing Commission for Public Health rules for shellfish sanitation that are incompatible or dissimilar with existing Marine Fisheries Commission (MFC) rules, requiring time to fully integrate or combine the rules that were formerly housed within two agencies. The proposed effective date of these rule changes is April 1, 2014.

#### Purpose of Rules:

Historically the Shellfish Sanitation Section, working under the Division of Environmental Health, implemented NSSP requirements for classifying growing areas as well as permitting and inspecting certified shellfish dealers. The DMF had responsibility for enforcing the harvest of shellfish and opening and closing shellfish waters by proclamation, under authority of the State Health Director and recommendation of the Shellfish Sanitation Section. In July 2011, the Division of Environmental Health was eliminated and the Shellfish Sanitation Section was merged with the DMF.

DMF staff, including the Shellfish Sanitation Section, believes this merger strengthens both groups and the close coordination provides a greater level of protection to shellfish consumers. However, during early attempts to integrate Commission for Public Health shellfish sanitation rules into MFC rules, several common areas were discovered where existing rules of the two agencies differ enough to create obstacles in effective implementation and enforcement of the more recent NSSP requirements. This primarily stems from the differences between public health-related rules and resource management-related rules. Attempts to combine or re-write rule areas that deal with harvester and dealer requirements revealed more changes that are needed in other supporting rules. As a result, the full integration of these rules may take several years to accomplish. In the mean time, North Carolina risks being in non-compliance with the NSSP's Model Ordinance if recent requirements adopted by the Interstate Shellfish Sanitation Conference (ISSC) are not implemented. The U.S Food and Drug Administration (FDA) annually evaluates dealer compliance with the Model Ordinance standards. Continued non-compliance with the Model Ordinance will likely result in disciplinary action and possible removal from the FDA's list of Interstate Certified Shellfish Shippers, thereby jeopardizing interstate shipment of all N.C. shellfish products. This would be highly detrimental to the state's shellfish growers, harvesters, and dealers.

Due to the time required for the permanent rule making process and relatively short implementation deadlines commonly required by the NSSP (often 6 months or less), the most efficient way to address existing and future changes to the Model Ordinance would be the use of proclamation authority by the DMF Director (Appendix 1). This authority would only be used to implement the minimum requirements adopted by the NSSP for public health protection and would not be used for addressing resource or management issues. If specific NSSP requirements are changed, the ability of the DMF Director to use this proclamation authority would greatly enhance the ability of the state to remain in compliance with the national program. This approach would not be dissimilar to current annual or seasonal adjustments or closures made by the DMF in accordance with the Atlantic States Marine Fisheries Commission where the DMF also uses proclamation authority for compliance with federal requirements. This flexibility is important because changes occur frequently that are outside the direct control of North Carolina. The NSSP usually allows a period of time for states to come into compliance with new requirements, but for some recent changes this has been as little as six months. Falling into non-compliance forces the state to operate under a corrective plan, monitored by FDA, and may jeopardize the interstate sale of North Carolina shellfish products.

The following is a summary of NSSP changes and requirements that have been adopted since 2009, which need to be fully implemented and/or enforced by the MFC as soon as possible to maintain federal compliance. While there may eventually be some differences from what appears below, this is the most current information available on what measures are currently in place or expected to be in place. The NSSP has submitted the following measures to participating states, signifying that these measures will be implemented:

1. Harvester Time-to-Temperature Limits (for Non-Vibrio Control Plan Shellfish)  
These NSSP Action Levels apply only to the original harvester or harvester/dealer of shellstock for the purposes of handling and transporting shellstock to the original dealer.

**Table 1. Harvest Limits**

<b>Action Level</b>	<b>Avg. Monthly Maximum Air Temperature</b>	<b>Maximum Hours from Exposure at Harvest to Receipt at a Certified Dealers Facility</b>	<b>Months that would apply in NC using NOAA climate data</b>
1	<50°F (10°C)	36 hours	N/A in North Carolina
2	50°F - 60°F (10°C - 15°C)	24 hours	Jan, Feb
3	60°F - 80°F (15°C - 27°C)	18 hours	March, April, May Oct, Nov, Dec
4	≥81° F (>27°C)	12 hours	June, July, Aug, Sept

2. Dealers Receiving Shellstock from a Harvester (Buying or Self Harvest by a Harvester/Dealer)

The following HACCP requirements have been added in the Model Ordinance for receiving shellstock.

- a. HACCP Record – The time the shellstock was received and placed under refrigeration must not exceed the action level in the table above.
- b. HACCP Record – The dealer must document that the shellstock was chilled to an internal temperature of 50°F prior to shipping the product. There are exceptions to this requirement:
  - Shipments less than four hours
  - Retail sale at the dealer’s certified facility
  - Shipments four hours or greater shipped with a Time Temperature Recorder (TTR). The TTR must show continuous cooling took place during transport.

3. Initial Dealers Shipping Shellstock

- a. Dealer trucks must be pre-chilled to 45°F prior to loading shellstock for shipment
- b. Common carrier trucks must be pre-chilled to be 45°F prior to loading shellstock for shipment.
- c. Invoices must contain the following:
  1. The shellstock internal (or shell) temperature
  2. The shipping container or truck temperature
  3. The time the container was loaded
  4. A statement that indicates the load has met the time/temperature requirements for harvest and chilling, OR
  5. A statement that indicates it has met the time temperature requirements for harvest, however was not pre-chilled to 50°F and has been shipped with a TTR.

4. Receiving Shellstock from another Certified Dealer (in or out of state)

Dealers may only accept shellstock intended for raw or undercooked consumption if the following conditions are met:

- a. The invoice indicates all time-to-temperature conditions were met
- b. The container or truck is 45°F or below, OR
- c. The shellstock internal (or shell) temperature is 50°F or below, OR
- d. The shellstock is adequately iced

- e. A TTR indicating that continuous cooling has occurred for shipments with invoices indicating pre-chilling of shellstock did not occur prior to shipment.

5. Restricted Use Shellstock

Some dealers not meeting the time-to-temperature requirements of state Vibrio management plans may elect to tag or label the product as “Restricted Use Shellstock”. This tag indicates that the product is to be shucked by a dealer or post-harvest processed. Although this product is not intended for raw or undercooked consumption, DMF inspectors still find this product being offered for sale in retail settings and currently have no legal authority to stop sale since it is legally tagged by a dealer.

6. Harvester and Dealer Training

Beginning in 2014, the Model Ordinance will require states to implement training and education programs for all shellfish harvesters and certified dealers. This training will be required every two years and will be a pre-requisite for licensing. The intent is to increase the awareness of temperature control and food handling practices for shellfish.

**Basic Economic Impact:**

The proposed rule changes and related management measures will help ensure public health and safety is upheld and enforced as well as help ensure a high quality, marketable product. It will also make certain that state shellfish harvesters and dealers maintain compliance with federal standards, thereby forgoing disciplinary actions that may jeopardize access to out of state markets that are vital to the viability of the state’s shellfish industry. The management measures are expected to impose both direct costs and opportunity costs to private sector participants as well as state government.

**Benefits:**

The proposed rule will allow state harvesters and dealers to maintain compliance with federal protocols in shellfish handling and shipment. This will prevent disciplinary measures from being levied for non-compliance of such protocols, thereby not jeopardizing the interstate shipment of North Carolina shellfish products. The rule changes will allow continued access to out of state markets which are vital to the viability of the commercial shellfish industry in the state. Revenues of dealers and harvesters would be adversely affected if shipments of shellfish were to be rejected due to the state of North Carolina not being in compliance with NSSP standards. The rule changes will also yield benefits to public health by continuing to ensure that shellfish are properly handled and labeled. Finally, the proposed rule changes will help encourage a higher quality product that will be more marketable and face less discard due to post-harvest shellfish mortality.

**Costs:**

Although measures stemming from the proposed rule will codify proper shellfish handling practices as defined by the NSSP, the extent that these practices will impose costs or go above and beyond common practice is difficult to distinguish. While pathogens are present in the coastal waters of North Carolina and the state’s shellfish products have likely lead to undocumented food-borne illnesses, there have been no documented shellfish related food-borne illnesses originating from North Carolina shellfish products according to records of DMF shellfish staff. This suggests general practices among most shellfish harvesters and dealers within the state are likely rigorous, with a focus on a quality product that is safe for human consumption.

The proposed rules will impose costs on some individuals such as opportunity costs from waiting for shellstock to cool before shipment or costs related to rejection of shellstock that does not meet NSSP storage or shipment standards; however there are no data available to accurately predict or quantify such total costs. Historically, there have not been any recalls of North Carolina harvested shellstock. With the exception of newly required harvester and dealer training, it is unknown how far the new NSSP measures are above or beyond current common practices of shellfish dealers. Dealers are already required to have a Hazard Analysis and Critical Control Point (HACCP) plan (15A NCAC 18A .0434 HACCP PLAN) as well as to store and ship shellfish at specified temperatures (Appendix 2).

Documentation requirements related to the NSSP measures are expected to impose only minimal additional costs, as harvesters or dealers already record similar information under rule 15A NCAC 03K .0109 SHELLFISH HARVESTER AND DEALER TAGS (see Appendix 2). Under this rule, harvesters and dealers must attach a tag to shellfish products that documents information such as the harvester's name, license information, and date of harvest. Newly mandated documentation stemming from the proposed rule changes may be included on this tag as well, thereby not imposing additional material costs. Additionally, there will be no additional costs for marine patrol, as officers are currently enforcing rule 15A NCAC 03K .0109. Officers will not need to expend additional time or effort to uphold new regulations that may occur from the proposed rule as enforcement activities are already occurring.

In addition to the above general statements on the expected costs of the NSSP measures, the following addresses the possible costs on an individual measure basis:

1. Harvester Time-to-Temperature Limits (for Non-Vibrio Control Plan Shellfish)

In North Carolina, shellfish harvest mostly occurs in cooler late fall, winter, and early spring months. Depending on the month, harvesters will have 12 to 24 hours to get their catch to a shellfish dealer. This will be a burden to some shellfish harvesters; however this is also likely well within the common practice of some shellfish harvesters in the state. Data is not available to differentiate how many harvesters may be adversely impacted by this requirement. As of 2012, there were more than 1,000 registered shellfish harvesters in the state.

2. Dealers Receiving Shellstock from a Harvester (Buying or Self Harvest by a Harvester/Dealer)

Dealers may incur opportunity costs by having to wait for their product to be chilled to 50°F prior to shipment. It is impossible to estimate this cost with any accuracy as chill time will vary by individual equipment and the length of time shellstock may remain under refrigeration prior to shipment will be highly variable. There will no equipment costs incurred, as dealers are already required to refrigerate their product at 50°F under rule 15A NCAC 18A .0711 SHELLSTOCK STORAGE (see Appendix 2).

3. Initial Dealers Shipping Shellstock

Dealers will likely face direct costs from the requirement of pre-chilling a carrier truck to 45°F before shellfish shipment. Direct costs will be incurred from fuel spent to pre-chill the vehicle. It is impossible to estimate these costs with any accuracy as chill time will vary by individual equipment and the number of dealer shipments is not tracked by the DMF. There are not anticipated equipment costs, as shellfish dealers are already required to provide refrigerated transportation for their product at 45°F under rule 15A NCAC 18A .0420 TRANSPORTING SHELLSTOCK (see Appendix 2).

4. Receiving Shellstock from another Certified Dealer (in or out of state)

This measure is not expected to impose costs, as it focuses on documentation that initial dealers shipping the shellstock have followed the appropriate measures.

5. Restricted Use Shellstock

This measure is not expected to impose many costs to shellfish dealers, as it applies to product that does not meet the time to temperature requirements. This is product purchased with the intention of offering a fully cooked product to the final consumer due to health risks associate with eating the product raw or undercooked. This measure requires it to be clearly labeled as such so as to not confuse it with shellstock that meets higher health standards.

6. Harvester and Dealer Training

Harvester and dealer training requirements will impose costs to both the private sector and state government. These costs will include direct costs of training materials for the state as well as opportunity costs for harvesters, dealers, and DMF staff. Estimated direct and opportunity costs to participants as well as the state are shown in Table 2 .

**Table 2. Estimated costs of proposed rule.**

	<b>Opportunity Costs</b>	<b>Travel Costs</b>	<b>Materials</b>	<b>Total Costs</b>
Dealers	\$9,100	\$5,900		<b>\$15,000</b>
Harvesters	\$54,200	\$34,700		<b>\$88,900</b>
<i>Private Sector Subtotal</i>	<i>\$63,300</i>	<i>\$40,600</i>		<i>\$103,900</i>
State Government	\$1,000		\$3,000	<b>\$4,000</b>
<b>Total Estimated Costs</b>	<b>\$64,300</b>	<b>\$40,600</b>	<b>\$3,000</b>	<b>\$107,900</b>

According to the DMF trip ticket program, in 2012 there were 195 shellfish dealers and 1,156 shellfish harvesters in the state, or a total of 1,351 participants. Training will be required every other year and the training course is expected to take approximately 2 hours. While commute distances will vary by participant, it is estimated that travel to training sessions will take approximately 1 hour round trip and will incur direct travel costs of \$30 per harvester or dealer. Therefore, the total estimated individual opportunity cost is 3 hours and individual direct cost is \$30. By multiplying the number of participants (1,351) by the estimated time expended on training (3 hours) and direct cost (\$30), the overall estimated time spent on training is 4,053 hours and the overall estimated direct travel cost is \$40,530. To monetize the opportunity costs for time spent at the training course and traveling, the appropriate total hourly compensation<sup>1,2</sup> of \$15.62 was multiplied by the estimated total time spent (4,053 hours) to provide an estimated total opportunity cost of about \$63,300. By adding the total opportunity cost and total direct cost together, the total cost for all participants is estimated to be about \$103,900.

<sup>1</sup> 2012 median hourly wage for farming, fishing, and forestry occupations in North Carolina according to the US Department of Labor Bureau of Labor Statistics. [http://www.bls.gov/oes/current/oes\\_nc.htm#13-0000](http://www.bls.gov/oes/current/oes_nc.htm#13-0000).

<sup>2</sup> Total compensation includes wages and benefits. This is estimated by adding 34% (the hourly state employee benefits rate) to the hourly wage. Since compensation data is not available for harvesters and dealers, it is assumed that the level of compensation is equal to that for state employees.

It is assumed that training sessions will be held monthly and will require the attendance of one DMF employee each session. While there will be no need to hire additional staff, there will be opportunity costs as the employee will take approximately 2.5 hours to setup and carry out each training session. Under this assumption, the harvester and dealer training will require 30 hours of DMF staff time per year. Applying an assumed total compensation<sup>2</sup> of \$33.21 per hour based on the salary of the appropriate position that will be involved in training, the total opportunity cost for the state is estimated to be \$996 per year. Training materials are estimated to cost \$3,000. Total estimated costs for the state are \$3,996 per year. Overall costs of the proposed rule for both the private sector and state government are expected to be \$107,852.

While the rule provides proclamation authority regarding product recall and recall procedures, this is not expected to have a significant impact based on historical data that indicates no recalls on NC shellfish products. Also, it is not expected that this rule change result in additional product recalls.

**Substantial Impact Declaration:**

The proposed rule is not expected to have a substantial economic impact based on information and data the Division currently has available. Depending on further changes in the Model Ordinance, there may be requirements introduced through proclamation that may have a significant impact on the regulated community. However, at this point, the Division cannot anticipate what those requirements may be or the size of their impact.

## Appendix 1:

### **Proposed Rule Changes:**

#### **15A NCAC 03K .0110 PUBLIC HEALTH AND CONTROL OF OYSTERS, CLAMS, SCALLOPS AND MUSSELS**

(a) To protect public health, the Fisheries Director may, by proclamation, impose any or all of the following restrictions on oysters, clams, scallops and mussels to ensure the sale or distribution of shellfish from approved sources and ensure shellfish have not been adulterated or mislabeled during cultivation, harvesting, processing, storage and transport, in compliance with the National Shellfish Sanitation Program Guide for Control of Molluscan Shellfish, Section II: Model Ordinance:

- (1) Specify time and temperature controls;
- (2) Specify sanitation control procedures as specified in 21 Code of Federal Regulations (CFR) Part 123.11;
- (3) Specify Hazard Analysis Critical Control Point (HACCP) requirements as specified in 21 CFR Part:
  - (A) 123.3 Definitions;
  - (B) 123.6 HACCP Plan;
  - (C) 123.7 Corrective Actions;
  - (D) 123.8 Verification;
  - (E) 123.9 Records; and
  - (F) 123.28 Source Controls;
- (4) Specify tagging and labeling requirements;
- (5) Establish training requirements for shellfish harvesters and certified shellfish dealers;
- (6) Require sales records and collection and submission of information to provide a mechanism for shellfish product to be traced back to the water body of origin; and
- (7) Require implicated product recall and specify recall procedures.

(b) Proclamations issued under this Rule shall suspend appropriate rules or portions of rules under the authority of the Marine Fisheries Commission as specified in the proclamation. The provisions of 15A NCAC 03I .0102 terminating suspension of a rule as of the next Marine Fisheries Commission meeting and requiring review by the Marine Fisheries Commission at the next meeting shall not apply to proclamations issued under this Rule.

*Authority G.S. 113-134; 113-182; 113-201; 113-221.1; 113-221.2; 143B-289.52*

## **Appendix 2:**

### **Referenced shellfish rules currently in place:**

#### **15A NCAC 03K .0109 SHELLFISH HARVESTER AND DEALER TAGS**

It is unlawful to possess or sell oysters, clams, or mussels in a commercial fishing operation without a harvest tag affixed to each container of oysters, clams or mussels. Tags shall be affixed by the harvester or dealer and shall meet the following criteria:

- (1) Tags shall be identified as harvest tags. They shall be durable for at least 90 days, water resistant, and a minimum of two and five-eighths inches by five and one-fourth inches in size.
- (2) Tags shall be securely fastened to the outside of each container in which shellstock is transported. A harvester or dealer tag shall be securely fastened to the outside of each container at a dealer location except, bulk shipments of shellfish in one container and from the same source may have one tag with all required information attached. Harvesters who are also certified shellfish dealers may use only their dealer tag if it contains the required information. The required information shall be included on all lots of shellfish subdivided or combined into market grades or market quantities by a harvester or a certified shellfish dealer.
- (3) Tags shall be attached to all shellfish stored at a dealer location.
- (4) Tags shall contain legible information arranged in the specific order as follows:
  - (a) The harvester's name, address and shellfish license or standard or retired standard commercial fishing license with shellfish endorsement number.
  - (b) The date of harvest.
  - (c) The most precise description of the harvest location as is practicable (e.g., Long Bay, Rose Bay) that can be easily located by maps and charts.
  - (d) Type and quantity of shellfish.
  - (e) The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS".

*Authority G.S. 113-134; 113-168.5; 113-169.2; 113-182; 113-221; 143B-289.52*

#### **15A NCAC 18A .0420 TRANSPORTING SHELLSTOCK**

- (a) All shellstock storage areas in trucks, buy boats, buy trucks, trailers, and other conveyances used for transporting shellstock shall be enclosed, tightly constructed, painted with a light color washable paint, kept clean, and shall be subject to inspection by the Division.
- (b) Shellstock shall be shipped under temperature and sanitary conditions in accordance with these Rules which will keep them alive and clean and will prevent adulteration or deterioration. All shellstock shall be kept under mechanical refrigeration at a temperature of 45°F (7.1°C) or below. All conveyances used to transport shellstock shall be equipped with an operating thermometer.
- (c) Buy boats and buy trucks shall be kept clean with water from a source approved by the Division under Rule .0413 of this Subchapter. Buy boats and buy trucks shall provide storage space for clean shipping containers, identification tags, and records.

*Authority G.S. 130A-230*

#### **15A NCAC 18A .0434 HACCP PLAN**

Each dealer shall have and implement a written HACCP Plan. The owner or authorized designee shall sign the plan when implemented and after any modification. The plan shall be reviewed and updated, if necessary, at least annually. The plan shall, at a minimum:

- (1) List the food safety hazards that are reasonably likely to occur;
- (2) List the critical control points for each of the food safety hazards;
- (3) List the critical limits that must be met for each of the critical control points;

- (4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
- (5) List any corrective action plans to be followed in response to deviations from critical limits at critical control points;
- (6) Provide a record keeping system that documents critical control point monitoring; and
- (7) List the verification procedures, and frequency thereof, that the dealer will use.

*Authority G.S. 130A-230*

**15A NCAC 18A .0711 SHELLSTOCK STORAGE**

- (a) Refrigeration of shellstock. Treated shellstock shall be placed in cold storage if they are not released immediately. The temperature for cold storage shall be 50°F (10°C) or lower. A refrigerated storage room shall be provided for depurated shellstock. All untreated shellstock shall be kept in a separate shellstock storage room. Measures shall be taken to prevent the unauthorized removal of any shellstock. All shellstock shall be handled and stored under sanitary conditions in accordance with the rules in this Subchapter.
- (b) Controlled storage. Shellstock which is received at the depuration facility which cannot be processed immediately shall be placed in controlled storage. In controlled storage the temperature shall be 50°F (10°C) or lower. A gradual change of temperature from the storage temperature to the depuration water temperature may then be necessary to insure proper treatment. Any shellstock which has been held under refrigeration at a depuration facility for more than 48 hours shall not be depurated.

*Authority G.S. 130A-230*