

NOTICE OF AGENCY RULE-MAKING ADOPTION

AGENCY: Department of Marine Resources

CHAPTER NUMBER AND TITLE: Chapter 115 *Vibrio parahaemolyticus* Control Plan

ADOPTED RULE NUMBER:
(LEAVE BLANK-ASSIGNED BY SECRETARY OF STATE)

CONCISE SUMMARY:
This rule incorporates the New Meadows River, north of Bath/State Rd in Brunswick and West Bath, into the existing *Vibrio parahaemolyticus* (*Vp*) control plan. The addition of the New Meadows River is intended to reduce the likelihood that American and European oysters (*Crassostrea virginica* and *Ostrea edulis*) and hard clams (*Mercenaria mercenaria*) harvested from the New Meadows River will cause *Vp* infections in consumers. Independent, biological sampling of hard clams (quahogs) in the New Meadows River has shown positive results for total *Vp*, so the organism is known to be present in the growing area. The Maine Department of Marine Resources recognizes that the New Meadows River has the environmental characteristics (primarily water and air temperature and salinity) that potentially pose a threat to public health with regard to *Vp* infections. Research indicates that the most reliable way to minimize potential *Vp* illnesses is to utilize time and temperature controls.

EFFECTIVE DATE:
(LEAVE BLANK-ASSIGNED BY SECRETARY OF STATE)

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Please approve bottom portion of this form and assign appropriate MFASIS number.

APPROVED FOR PAYMENT _____					DATE: _____
FUND	AGENCY	S-UNIT	APP	OBJT	AMOUNT
010	13A	1120	10	4946	regulations

Please forward invoice to: Natural Resource Service Center, 155 SHS, Augusta

DEPARTMENT OF MARINE RESOURCES

Chapter 115 - *Vibrio parahaemolyticus* Control Plan

115.01 Compliance

The *Vibrio parahaemolyticus* Control Plan (the “Vibrio Control Plan” or the “Control Plan”) applies specifically to American and European Oysters (*Crassostrea virginica* and *Ostrea edulis*) and Hard Clams (*Mercenaria mercenaria*) harvested from the Damariscotta River and the New Meadows River. The Control Plan provides additional and more rigorous controls than those imposed by DMR Rules Chapters 9, 15, 16, 17, 18, 19, 20 and 22 to the handling of American and European Oysters and Hard Clams in the area described in Section 115.02. Insofar as the Control Plan time and temperature requirements exceed those imposed by existing rules or are in addition to those imposed by existing rules, the relevant provisions of the Control Plan shall supersede the provisions of Chapters 9, 15, 16, 17, 18, 19, 20 and 22.

The Control Plan shall be complied with during the harvesting and handling of the above-described species, as conducted by harvesters, certified shellstock dealers, certified shellfish establishments (sometimes referred to as shellfish facilities or plants), shucker-packers, shellstock shippers and receivers, reshippers, depuration processors, enhanced retail seafood license holders and all others involved in the processes described in Chapters 9, 15, 16, 17, 18, 19, 20 and 22.

115.02 Control Months and Locations

The Vibrio Control Plan is in effect from May 1st through October 31st, inclusive, in all parts of the Damariscotta River north of a line beginning at Montgomery Point, Boothbay and running southeast to Jones Point, South Bristol and in all parts of the New Meadows River north of Bath/State Rd in Brunswick and West Bath. A mandatory harvest/purchase plan must be submitted annually by March 1 in accordance with section 115.04 (F).

115.03 Definitions

“**Adequately iced**” means that the amount and application of ice is sufficient to ensure that immediate cooling begins and continues for all shellstock in a container. If ice slurry is used and the shellstock are submerged, the presence of ice in the slurry indicates adequate icing. Potable water must be used for the production of ice used for cooling of shellstock.

“**Control months**” means May 1st through October 31st, inclusive

“**Harvest**” means the act of removing shellstock from growing area waters and its placement on or in a manmade conveyance or other means of transport or transfer. This does not include the placement of shellstock in aquaculture gear designed to grow or enhance shellstock as part of husbandry practices.

“**Husbandry**” means the production, development, or improvement of a marine organism.

“**Mechanical Refrigeration**” means storage in a container or conveyance that is approved by the Maine Department of Marine Resources (DMR) and capable of cooling to, and maintaining, an ambient temperature of 45°F or less.

“**Potable water**” means a water supply which meets the requirements of the Safe Drinking Water Act, as administered by the EPA and which meets the requirements of DMR Chapters 15-20.

“**Resubmerge**” means, and is strictly limited to, reintroduction of shellstock into approved waters following the removal of shellstock from approved waters. This is separate and distinct from “wet storage” which is a certified dealer activity. Resubmergence shall be conducted only by an aquaculture lease or permit holder ~~or a certified dealer~~.

“**Shading**” means to shelter by intercepting the direct rays of the sun to protect the shellstock from heat. Shading may be accomplished by any means that effectively protects the harvested shellstock from direct sunlight and prevents excessive heat build-up in the shaded area. Materials used for shading should not be in direct contact

with the shellstock unless they are food grade surfaces (e.g. no seaweed or wet tarps applied directly to shellstock).

“**Temperature control**” means the use of ice or mechanical refrigeration, which is capable of lowering the temperature of the shellstock and maintaining it at an internal temperature of 50°F or less.

“**Time of harvest**” for the purpose of temperature control begins once the first shellstock is no longer submerged. For example, the time intertidal shellstock are first exposed to the air as the tide recedes or the time when a drag is brought onboard a vessel with shellstock from a subtidal resource.

“**Vp**” and “**Vibrio**” refer to *Vibrio parahaemolyticus*

115.04 General Requirements

- A. Deterioration and Decomposition. Harvesters shall not allow shellstock to deteriorate or decompose from exposure to high ambient air temperatures and shall deliver shellstock to a certified shellfish dealer before such deterioration or decomposition occurs.

Certified shellfish dealers shall not allow shellstock to deteriorate or decompose from exposure to high ambient air temperatures and shall deliver shellstock to a certified shellfish dealer or retail customer before such deterioration or decomposition occurs.

- B. Sales from Home Prohibited. Notwithstanding the provisions of 12 MRS §6601 (2), during the control months it is unlawful for harvesters to sell from their homes oysters and hard clams that have been taken from the Damariscotta River and the New Meadows River.
- C. Recreational Harvest Prohibited. It is unlawful to engage in the recreational harvest of oysters and hard clams harvested from the Damariscotta River and the New Meadows River during the control months. Provided, however, that the prohibition against recreational harvest shall not apply to those holding a Limited Purpose Aquaculture license for shellfish taken from their license site.
- D. Mandatory Training. All harvesters and certified shellfish dealers who take oysters and/or hard clams from the Damariscotta River and the New Meadows River or who purchase oysters and/or hard clams from harvesters that were taken from the Damariscotta River and the New Meadows River shall participate in an annual, mandatory training provided by the DMR. Any harvester or dealer whose product is implicated in an epidemiologically linked case of Vibrio illness shall take a refresher training provided by DMR.
- E. Mandatory Ambient Air Temperature Records. All harvesters who take oysters and/or hard clams from the Damariscotta River shall use one of two methods to record ambient air temperature: a continuous ambient air temperature data recorder with a record on the harvester’s temperature collection data sheet of the maximum air temperature at during the time of harvest ~~and at the end of harvest activities~~; or data collected from a DMR-designated weather station with a record of the maximum air temperature at during the time of harvest ~~and at the end of harvest activities~~. Any harvester or dealer whose product is implicated in an epidemiologically linked case of Vp shall provide their continuous ambient air temperature data recorder to DMR ~~for review if applicable,~~ otherwise the maximum recorded air temperature from the DMR-designated weather station will be used.
- F. Mandatory Vp Harvest Plan By March 1. All harvesters and certified shellfish dealers who take oysters and/or hard clams ~~or, buy or~~ buy or wet store oysters and/or hard clams from the Damariscotta River and the New Meadows River shall submit to DMR a Vp harvest/purchase plan. This plan must be submitted on or before March 1st annually in order to be able to operate during the control months. The harvest/purchase plan must be reviewed, amended if necessary, signed and dated by the harvester or shellfish dealer before submission to DMR. The DMR will approve or deny the plan within 30 days and notify the applicant in writing of their decision. If the plan is denied, the applicant will have an opportunity to correct the deficiencies. Harvesters and shellfish dealers may not harvest ~~or, buy or~~ buy or wet store oysters or hard clams during the control months without a DMR approved harvest/purchase plan. The harvest/purchase plan must include;

(1) For harvesters:

- a. Harvest process from time of harvest to delivery to a certified shellfish dealer ~~for wet storage or achievement of an internal temperature of 50°F.~~

- b. Temperature collection including recording the daily maximum air temperature during the harvest at the start of harvest activities and at the end of harvest activities. An example data sheet should be included with the ~~harvest~~ plan.
- c. Cooling processes such as resubmergence procedures, shading, wetting and icing and wet storage.
- d. Product handling and data recording including documentation of temperature history and resubmergence times. Details on how lots are identified and kept separate depending on their exposure history must be included. An example data sheet should be included with the ~~harvest~~ plan.
- e. Conveyance methods including how shellstock are held and transported from time of harvest to point of sale, resubmergence or wet storage.

(2) For Dealers:

- a. Receiving process including documentation of maximum air temperature during harvest, time of harvest, verification of harvesters' training and harvest plan requirements and time of delivery.
- b. Temperature control measures and documentation that ensures product reaches 50°F internal temperature within ten hours of receiving product.
- c. Provisions for maintaining and continuing cooling that was initiated by the harvester.

115.05 Harvest Restrictions During Control Months

A. For the Damariscotta River

- (1) The temperature shall be determined at the time of harvest using a continuous ambient air temperature data recorder or data from a DMR-designated weather station and recorded on the temperature collection data sheet.
- (2) All oysters and hard clams shall be transferred to a certified shellfish dealer within five (5) hours of the time of harvest and put into temperature control.
- (3) All oysters and hard clams shall be subject to shading immediately after harvest.
- (4) All oysters and hard clams that are harvested and exposed to ambient temperatures for more than five (5) hours but less than twelve (12) hours must be resubmerged or wet stored by a certified shellfish dealer for no less than 24 hours.
- (5) All oysters that are harvested and exposed to ambient temperatures for twelve (12) hours or more must be resubmerged or wet stored for no less than seven (7) days or 168 hours.

B. For the New Meadows River

- (1) All oysters and hard clams shall be subject to shading immediately after harvest.
- (2) All oysters and hard clams shall be adequately iced onboard immediately after harvest and maintained on ice until delivery to a certified dealer

115.06 Additional Harvest Restrictions During Control Months For 80° F and above Air Temperatures for the Damariscotta River

The temperature shall be determined at the time of harvest using a continuous ambient air temperature data recorder or data from a DMR-designated weather station and recorded on the temperature collection data sheet.

All oysters and hard clams shall be transferred to a certified shellfish dealer within two (2) hours of the time of harvest and put into temperature control.

All oysters and hard clams shall be subject to shading immediately after harvest.

All oysters and hard clams that are harvested and exposed to ambient temperatures for more than two (2) hours but less than twelve (12) hours must be resubmerged or wet stored by a certified shellfish dealer for no less than twenty-four (24) hours.

All oysters that are harvested and exposed to ambient temperatures for twelve (12) hours or more must be resubmerged or wet stored for no less than seven (7) days or 168 hours.

115.07 Noncompliance

Shellstock received by a certified dealer without time of harvest recorded on the harvest tag shall be resubmerged in an approved wet storage system for seven (7) days or 168 hours or destroyed.

115.08 Reporting of Violations

Harvesters and certified shellfish dealers are required to report observed violations of the ~~Damariscotta River~~ Vibrio Control Plan immediately to Marine Patrol.

115.09 Effective Date

The effective date of Chapter 115 shall be January 1, 2016.

Basis Statement

This regulation incorporates the New Meadows River, north of Bath/State Rd in Brunswick and West Bath, into the existing *Vibrio parahaemolyticus* (*Vp*) control plan. The addition of the New Meadows River is intended to reduce the likelihood that American and European oysters (*Crassostrea virginica* and *Ostrea edulis*) and hard clams (*Mercenaria mercenaria*) harvested from the New Meadows River will cause *Vp* infections in consumers. Independent, biological sampling of hard clams (quahogs) in the New Meadows River has shown positive results for total *Vp*, so the organism is known to be present in the growing area. The Maine Department of Marine Resources recognizes that the New Meadows River has the environmental characteristics (primarily water and air temperature and salinity) that potentially pose a threat to public health with regard to *Vp* infections. Research indicates that the most reliable way to minimize potential *Vp* illnesses is to utilize time and temperature controls.

Based on comments received, the Department has removed the New Meadows River from the 115.04(E) mandatory ambient air temperature records as 115.05(B)(2) requires icing immediately after harvest for the New Meadows River. The Department also added a provision to the dealer plan that requires dealers to indicate how they will maintain and continue cooling of the product that was initiated by the harvester. These modifications are intended to avoid redundancies in the regulation and to ensure proper temperature controls are maintained after harvest.

Summary of Comments

Notice of this proposed rulemaking appeared on September 13, 2017 in the five major daily newspapers as published by the Secretary of State. On September 13, 2017, the rule was posted on the DMR website, and electronic messages were sent to individuals who subscribe to DMR notices. Public hearings were advertised in compliance with the procedures outlined in the Maine Administrative Procedures Act and were held on October 4, 2017 at 5pm at the Bath Recreation Center, Bath. The comment period closed October 16, 2017.

Public Hearing

Bath Parks and Recreation Center

October 4, 2017

5pm

No members of the public attended the hearing. The Department was represented by Deirdre Gilbert, Kohl Kanwit, and Amanda Ellis.

Written Comments:

Neutral (2)

Terry Watson, submitted via email on October 4, 2017:

Hi , my name is Terry Watson and am writing in response to the proposed rule changes for the harvest of shellfish on the upper new meadows river . 115.04 E mandatory ambient air temperature records, should not apply on the New Meadows River, as the icing immediately after harvest, brings the temperature down to appropriate temperatures. They also need to remain on ice until delivered to the dealers which means the air temperature is no longer a factor. Thank you Terry Watson

Department response:

To avoid redundancies in the regulation, the Department will remove the New Meadows River from the 115.04(E) mandatory ambient air temperature records as 115.05(B)(2) requires icing immediately after harvest for the New Meadows River.

Angel Wilson, DMR staff member, submitted via email on October 3, 2017:

Good afternoon Amanda. I am writing to share an incident I observed during a routine inspection at a shellfish dealer. Several separate harvesters brought in hard clams over the course of more than 2 hours I was there. All remaining in bags on a pallet on an 80 plus degree day, they believe they h Ave 10 hours to get then in cooler if they are brought in iced. There needs to be more clarification in the regulation defining the responsibility of the dealer in regards to the cooling process.

Here are the recommended changes:

115.05 Harvest Restrictions During Control Months

(2) For Dealers:

a. Receiving process including documentation of maximum air temperature during harvest, time of harvest, verification of harvesters' training and harvest plan requirements and time of delivery.

- b. Temperature control measures and documentation that ensures product reaches 50°F internal temperature within ten hours of receiving product.*
- c. Provisions for maintaining and continuing cooling that was initiated by the harvester.*

Department Response

To ensure proper temperature controls, the Department will add a provision to the dealer plan that requires dealers to indicate how they will maintain and continue cooling of the product that was initiated by the harvester.

Rule-Making Fact Sheet

(5 M.R.S., §8057-A)

AGENCY: Department of Marine Resources

NAME, ADDRESS, PHONE NUMBER OF AGENCY CONTACT PERSON:

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web address: <http://www.maine.gov/dmr/rulemaking/>

CHAPTER NUMBER AND RULE: Chapter 115 *Vibrio parahaemolyticus* Control Plan

STATUTORY AUTHORITY: 12 M.R.S. § 6171-A

DATE AND PLACE OF PUBLIC HEARING(S): October 4, 2017 5 PM, Bath Parks and Recreation Center, Bath ME

COMMENT DEADLINE: October 16, 2017

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [see §8057-A(1)(A)&(C)]

This proposed rule incorporates the New Meadows River, north of Bath/State Rd in Brunswick and West Bath, into the existing *Vibrio parahaemolyticus* (*Vp*) control plan. The addition of the New Meadows River is intended to reduce the likelihood that American and European oysters (*Crassostrea virginica* and *Ostrea edulis*) and hard clams (*Mercenaria mercenaria*) harvested from the New Meadows River will cause *Vp* infections in consumers. Independent, biological sampling of hard clams (quahogs) in the New Meadows River has shown positive results for total *Vp*, so the organism is known to be present in the growing area. The Maine Department of Marine Resources recognizes that the New Meadows River has the environmental characteristics (primarily water and air temperature and salinity) that potentially pose a threat to public health with regard to *Vp* infections. Research indicates that the most reliable way to minimize potential *Vp* illnesses is to utilize time and temperature controls.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___ YES ___ X NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [see §8057-A(1)(B)&(D)]

The regulation applies to persons engaged in the harvesting and handling of American and European oysters and hard clams grown in the New Meadows River.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE

Independent, biological sampling of hard clams and quahogs in the New Meadows River has shown positive results for total *Vp*, so the organism is known to be present in the growing area. The Maine Department of Marine Resources recognizes that the New Meadows River has the environmental characteristics (primarily water and air temperature and salinity) that potentially pose a threat to public health with regard to *Vp* infections. Research indicates that the most reliable way to minimize potential *Vp* illnesses is to utilize time and temperature controls.

ESTIMATED FISCAL IMPACT OF THE RULE: [see §8057-A(1)(C)]

Enforcement of these amendments will not require additional activity in this Agency. Existing enforcement personnel will monitor compliance during their routine patrols.

FOR EXISTING RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:

[see §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [see §8057-A(2)(B)]

BENEFITS OF THE RULE: [see §8057-A(2)(C)]

