

## Notice of Agency Rule-making Proposal

AGENCY: 13-188-Department of Marine Resources

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

TYPE OF RULE (*check one*):         Routine Technical         Major Substantive

PROPOSED RULE NUMBER (*leave blank; to be assigned by Secretary of State*):

**BRIEF SUMMARY:** Under current regulation, certain areas of Maine’s territorial waters are subject to a Control Plan for *Vibrio parahaemolyticus* between June 1 and October 15. This proposed rule-making would protect consumers from all species of *Vibrio* by extending these requirements for oysters to all of Maine’s territorial waters during these months. The requirements for hard clams are limited to the upper New Meadows River through this proposed rule-making. With the extension of these restrictions, harvester sales of oysters and upper New Meadows River hard clams from their homes would be prohibited during these months. The recreational harvest of oysters and upper New Meadows River hard clams would also be prohibited during these months, except for holders of Limited Purpose Aquaculture licenses removing oysters from their license sites, or in municipalities providing mandatory *Vibrio* training to recreational harvesters prior to licensing. The proposed rule eliminates a current requirement to submit an annual harvest/purchase plan. It requires mandatory annual Department provided training for all oyster and some hard clam harvesters and certified shellfish dealers purchasing oysters or upper New Meadows River hard clams. It provides two options for methods for harvesters to follow to reduce time to temperature for oysters and upper New Meadows River hard clams. Finally, it removes the option of wet storing to remediate product that has not been subject to the appropriate time to temperature controls.

Date, time and location of PUBLIC HEARING (*if any*): February 12, 2024, 5:30 p.m. in-person at the Sorrento-Sullivan Rec Center, 1776 US-1 Sullivan, ME. February 13, 2024, 5:00 p.m in-person at the Marquardt Building, Room 118, 32 Blossom Lane, Augusta or remotely via Microsoft Teams. Remote access information is posted to DMR’s website under “Meetings.”

COMMENT DEADLINE: February 23, 2024

CONTACT PERSON FOR THIS FILING (*include name, mailing address, telephone, fax, TTY, e-mail*):

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CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT (*if different*): Same

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES (*if any*): None

STATUTORY AUTHORITY FOR THIS RULE: 12 MRS 6171-A

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (*if different*): Same

AGENCY WEBSITE: <http://www.maine.gov/dmr/rulemaking/>

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**DEPARTMENT OF MARINE RESOURCES**

**Chapter 115: *Vibrio parahaemolyticus* VIBRIO CONTROL PLAN**

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### 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*) harvested in Maine territorial waters and hard clams (*Mercenaria mercenaria*) harvested in the upper New Meadows River designated control areas. The Control Plan provides additional and more rigorous controls than those imposed by DMR Rules chapters 9, 22 and 94 to the handling of American and European oysters and hard clams in the areas 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, 22 and 94.

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, aquaculture license holders, and retail seafood license holders and all others involved in the processes described in chapters 9, 22, and 94.

### 115.02 Control Months and Designated Control Areas

The Vibrio Control Plan is in effect from June 1<sup>st</sup> through October 15<sup>th</sup>, inclusive, in the designated control areas for the designated species:

- A. Maine territorial waters for American and European oysters (*Crassostrea virginica* and *Ostrea edulis*)
- B. all parts of the New Meadows River north of Bath/State Rd in Brunswick and West Bath for hard clams (*Mercenaria mercenaria*)
- C. ~~all parts of the Damariscotta River north of a line beginning at Montgomery Point, Boothbay and running southeast to Jones Point, South Bristol~~
- D. ~~all parts of the Sheepscot River north of Route 1~~
- E. ~~all parts of the New Meadows River north of Bath/State Rd in Brunswick and West Bath~~
- F. ~~all parts of the Scarborough and Nonesuch Rivers north of a line beginning at the eastern tip of Pine Point Beach, Scarborough and running east to the opposite shore on Prouts Neck, Scarborough~~
- G. ~~all parts of Spinney Creek north of Route 103~~
- H. ~~all parts of the Weskeag River north of a line beginning at the shore at the end of Ballyhac Rd. in Owls Head, running west to the north tip of Spaulding Island, then west to the opposite shore at Pleasant Beach in South Thomaston.~~

~~A mandatory harvest/purchase plan must be submitted annually by April 1<sup>st</sup> in accordance with section 115.04 (E).~~

### 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 June 1<sup>st</sup> through October 15<sup>th</sup>, 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.

**“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~~ 94.

**“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 holder or ~~permit~~ license holder.

**“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 time of harvest 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” refers to several species of pathogenic bacteria including but not limited to *Vibrio parahaemolyticus*.~~

### 115.04 General Requirements

- A. **Deterioration and Decomposition.** Harvesters shall not allow shellstock to deteriorate or decompose from exposure to high warm ambient air temperatures (>60°F) and shall deliver shellstock to a certified shellfish dealer before such deterioration or decomposition occurs.

Certified shellfish dealers, ~~and~~ enhanced retail seafood license holders and retail seafood license holders shall not allow shellstock to deteriorate or decompose from exposure to high warm ambient air temperatures (>60°F). ~~and~~ Certified shellfish dealers and enhanced retail seafood license holders shall cool shellstock to 50°F internal temperature within three hours of receiving product. Product may not be reshipped before it reaches 50°F internal temperature and must remain at or below 50°F internal temperature throughout distribution. Certified shellfish dealers may wet store or dehydrate with proper permitting ~~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) or §6810-B, during the control months it is unlawful for harvesters to sell from their homes oysters and hard clams that have been taken from the designated control areas.

- C. **Recreational Harvest Prohibited.** It is unlawful to engage in the recreational harvest of oysters and hard clams harvested from the designated control areas 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 or to towns with a municipal shellfish ordinance that issues recreational licenses and administers mandatory vibrio education to recreational harvesters prior to licensing.

- ~~D.~~ **Mandatory Training.** All harvesters, aquaculture license holders (issued under 12 MRS §6810-B), enhanced retail seafood license holders and certified shellfish dealers who take oysters and/or hard clams from the designated control areas or who purchase oysters and/or hard clams from harvesters that were taken from the designated control areas shall participate in annual, mandatory training provided by the DMR. Individuals are eligible to receive their Vibrio certification upon successful completion of the mandatory training. 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. **Vibrio Certification.** All harvesters, aquaculture license holders (issued under 12 MRS §6810-B), enhanced retail seafood license holders and certified shellfish dealers who take oysters and/or hard clams from the designated control areas or who purchase oysters and/or hard clams from harvesters that were taken from the designated control areas must obtain a Vibrio certification

- F. **Dealer Records.** Certified shellfish dealers and enhanced retail seafood license holders must document in their receiving records, the time of harvest, verification of harvesters' Vibrio certification, time of receipt and presence of adequate ice if applicable. Certified shellfish dealers and enhanced retail seafood license holders must record the time product reached 50°F or less internal temperature.

- G. **Buying Stations.** Certified shellfish dealers with a buying station permit may purchase oysters and/or hard clams from the designated control areas provided that they use

adequate icing to initiate immediate cooling in the conveyance. The use of mechanical refrigeration alone is not permitted.

H. **Inspection.** Any harvester, certified shellfish dealer, enhanced retail seafood license holder and/or retail seafood license holders whose product is implicated in an epidemiologically linked case of Vibrio illness shall be subject to an inspection by DMR to determine their compliance with Chapter 115 requirements.

~~I. **Mandatory Vp Harvest/Purchase Plan By April 1<sup>st</sup>.** All harvesters, certified shellfish dealers and enhanced retail seafood license holders who take oysters and/or hard clams, buy or wet store oysters and/or hard clams from the designated control areas shall submit to DMR a Vp harvest/purchase plan on DMR approved forms. This plan must be submitted on or before April 1<sup>st</sup> 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, shellfish dealer or enhanced retail seafood license holder 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, shellfish dealers and enhanced retail seafood license holders may not harvest, 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 or enhanced retail seafood license holder.~~
- ~~b. Cooling processes such as resubmergence procedures, shading, wetting, and icing.~~
- ~~c. Product handling and data recording including 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 plan.~~
- ~~d. Conveyance methods including how shellstock are held and transported from time of harvest to point of sale, resubmergence or wet storage.~~
- ~~e. Contingency plan if control plan is violated including resubmergence for aquaculture lease or permit holders, wet storage by a certified shellfish dealer or destruction of shellstock.~~

~~(2) For Dealers and Enhanced Retail Seafood License Holders:~~

- ~~a. Receiving process including documentation of 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 three hours of receiving~~

~~product. Product may not be reshipped before it reaches 50°F internal temperature.~~

- ~~e. Provisions for maintaining and continuing cooling that was initiated by harvesters utilizing Control Plans with immediate icing.~~
- ~~d. Dealers with a buying station permit may purchase oysters and/or hard clams from the designated control areas provided that they use ice to initiate immediate cooling in the conveyance.~~
- ~~e. Contingency plan if control plan is violated including resubmergence for aquaculture lease or permit holders, wet storage by a certified shellfish dealer or destruction of shellstock.~~

### 115.05 Harvest Restrictions During Control Months

Harvesters are required to use one of the following methods to reduce time to temperature for all oysters and hard clams taken from the designated control areas during the control months:

- A. ~~Control Plans that do not include immediate icing~~ Transfer of oysters and hard clams to a certified shellfish dealer or enhanced retail seafood license holder within two hours of harvest:
  - (1) All oysters and hard clams shall be transferred to a certified shellfish dealer or enhanced retail seafood license holder and put into temperature control, wet storage or depuration within two (2) hours of the time of harvest.
  - (2) All oysters and hard clams shall be subject to shading immediately after harvest.
  - (3) 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 on an aquaculture lease or license site ~~or wet stored by a certified shellfish dealer~~ for no less than 24 hours or destroyed.
  - (4) All oysters and hard clams that are harvested and exposed to ambient temperatures for twelve (12) hours or more must be resubmerged on an aquaculture lease or license site ~~or wet stored~~ for no less than seven (7) days or 168 hours or destroyed.
  - (5) Aquaculture lease or license holders who resubmerge shall maintain records identifying individual lots and their exposure history along with the date and time product was initially resubmerged and the date and time when the product was removed from resubmergence. These records shall be made available to DMR on request.
- B. ~~Control Plans that include~~ Immediate icing:
  - (1) All oysters and hard clams shall be subject to shading immediately after harvest.

- (2) All oysters and hard clams shall be adequately iced immediately after harvest and maintained on ice until delivery to a certified dealer or enhanced retail seafood license holder under the time to temperature regulations in Chapter 94.04.

#### **115.076**~~Noncompliance~~

Shellstock received by a certified dealer or enhanced retail seafood license holder without time of harvest recorded on the harvest tag, in exceedance of two (2) hours from time of harvest and/or without adequate ice shall be ~~placed in an approved wet storage system for seven (7) days or 168 hours or~~ destroyed. Shellstock received by a retail seafood license holder in exceedance of 50°F internal temperature shall be destroyed.

#### **115.087**~~Reporting of Violations~~

Harvesters, ~~and~~ certified shellfish dealers, enhanced retail seafood license holders and retail seafood license holders are required to report observed violations of the Vibrio Control Plan immediately to Marine Patrol.

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

STATUTORY AUTHORITY: 12 MRSA 6171-A

DATE AND PLACE OF PUBLIC HEARING(S): February 12, 2024, 5:30 p.m. in-person at the Sorrento-Sullivan Rec Center, 1776 US-1 Sullivan, ME. February 13, 2024, 5:00 p.m in-person at the Marquardt Building, Room 118, 32 Blossom Lane, Augusta or remotely via Microsoft Teams. Remote access information is posted to DMR's website under "Meetings."

COMMENT DEADLINE: February 23, 2024

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

This rule is proposed in order to expand the application of the existing *Vibrio parahaemolyticus* (Vp) control plan from certain areas, to all of Maine's territorial waters for oysters. The purpose of this change is to reduce the likelihood that American and European oysters (*Crassostrea virginica* and *Ostrea edulis*) harvested from Maine territorial waters will cause *Vibrio* infections in consumers. Increasingly, Maine's territorial waters have environmental characteristics (primarily water and air temperature and salinity) that potentially pose a threat to public health with regard to *Vibrio* infections. Research indicates that the most reliable way to minimize potential *Vibrio* 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 proposed regulations would apply to persons engaged in the harvesting and handling of American and European oysters and hard clams during the control period, requiring the use of certain methods to ensure time to temperature requirements are met.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B]: In August 2023, Maine experienced its first *Vibrio* illness outbreak. Six people were confirmed to have been made ill from consuming raw oysters that were harvested in Casco Bay and between two and four additional cases were considered probable. The causative agent was *Vibrio fluvialis*. The illness outbreak resulted in a 10-week closure of a harvest area and ultimately post-harvest handling was determined to be the likely cause of the illnesses. The implicated harvest area was not included in the existing *Vibrio* Control Plan and the illness outbreak likely could have been avoided if *Vibrio* controls were in place. Rapid cooling to 50°F or less has been proven to prevent growth of *Vibrio* bacteria in bivalve shellfish (Managing *Vibrio* Risk in Oysters, DePaola, A., Food Production Trends. Vol 39, Issue 4:p.338-347). Because there has not been an illness outbreak associated with hard clams outside of the upper New Meadows River, hard clams were not included in the statewide expansion of *Vibrio* controls.

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

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