

NOTICE OF AGENCY RULE-MAKING ADOPTION**AGENCY:** Department of Marine Resources**CHAPTER NUMBER AND TITLE:** Chapter 115 *Vibrio parahaemolyticus* Control Plan**CONCISE 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 rule-making protects 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 rule-making. With the extension of these restrictions, harvester sales of oysters and upper New Meadows River hard clams from their homes are prohibited during these months. The recreational harvest of oysters and upper New Meadows River hard clams is also 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 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.

ADOPTED RULE NUMBER:

(LEAVE BLANK-ASSIGNED BY SECRETARY OF STATE)

EFFECTIVE DATE:

(LEAVE BLANK-ASSIGNED BY SECRETARY OF STATE)

AGENCY CONTACT PERSON:

Deirdre Gilbert

AGENCY NAME:

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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 1st through October 15th, 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 Ballyhae 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 1st 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 1st through October 15th, 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 1st.** 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 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, 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.

Basis Statement

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 rule-making protects 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 rule-making. With the extension of these restrictions, harvester sales of oysters and upper New Meadows River hard clams from their homes are prohibited during these months. The recreational harvest of oysters and upper New Meadows River hard clams is also 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 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.

Summary of Comments

On January 24, 2024, the rule was posted on DMR’s website. Notice was also published on January 24, 2024 in the five major daily newspapers by the Secretary of State; and electronic messages were sent to individuals who subscribe to DMR’s rulemaking, shellfish and aquaculture notices. A public hearing was held February 12, 2024, 5:30 p.m. in-person at the Sorrento-Sullivan Rec Center, 1776 US-1 Sullivan, ME and February 13, 2024, 5:00 p.m in-person at the Marquardt Building, Room 118, 32 Blossom Lane, Augusta and remotely via Microsoft Teams.

The 2/12/2024 hearing was attended by the following individuals, and one comment was received at the hearing.

Name	Affiliation
Deirdre Gilbert, Kohl Kanwit	Maine Department of Marine Resources
Graham Platner, Alex de Koning	Members of the Public

The 2/13/2024 hearing was attended by the following individuals and one comment was received at the hearing.

Name	Affiliation
Deirdre Gilbert, Kohl Kanwit	Maine Department of Marine Resources
Terry Watson, Sally Watson, Lydia Trainor, Luke Saindon, Colin Casey	Members of the Public

Public Hearing Comment February 12, 2024 Sorrento

Graham Platner, Frenchman Bay Oyster Company, Sorrento

My only concern is that it's already pretty hard for smaller farms to get product to market. Having to get a facility in place to be your own dealer I think can be almost onerous for much smaller farms. Up until that point, I think that's only been a big problem down south. With this, if you can't sell from home anymore, you know, I think it becomes much more difficult. We've been doing Vibrio control stuff since we started doing this. So I don't think there's anything onerous about that. I hope that the DMR can look at how the dealer licensing works. I know this all comes under the Interstate Shellfish Compact and it's all borderline impossible to change. But right now, what we've been doing – I get those hobo loggers. I put them in the cooler the moment they come out of the water and they are to market within 30 minutes, mostly because we sell just locally. We have a facility, and frankly that's just because my mother used to have a smokehouse, and we can do that. But a lot of smaller farms don't have exactly that, so taking away the ability for folks to be able to sell from their homes and not adding in something on the dealer side to make it easier for people to sell without going through a dealer, or to get an enhanced retail in a way that they can utilize the technology that currently exists, like hobo loggers, instead of having to build a specific facility, cause right now...honestly I have no problem with any of this, but it's going to drive people to go through dealers more and that can really hammer small farms. You make a lot of your money off of direct sales. Once you start going through any of the big dealers, sometime your price gets cut in half. And that's pretty substantial. I would just ask you to be able to revisit some of the other stuff as well.

Public Hearing Comment, February 13, 2024 Augusta

Terry Watson, Clam Hunter, Phippsburg

The one thing that gets under my skin – the certified dealers, we are already being inspected, we are already following the rules that you put forth because we are inspected all the time. So, you would know if weren't doing it when the inspectors come, several times a year. We have to have a place for them to come to – the whole bit. And I really do agree that everyone should have to take the class to get into any of this, because I have seen some things over the years that were just...I couldn't believe that educated people didn't know better than that. My biggest issue right now is the annual training classes. I've never liked busy work and once you put that in, you have to come up every year with new things or go over the same things over and over and over....right now, waiting for my lease – I applied for a 20 year lease – I just can't imagine having to take 20 year's worth of classes just to keep growing oysters, because financially I was wiped out on the clams when they put the flow gauge on the Kennebec River. One other thing that I would like to add to this is I would really like to have states that are not really really closely complying with what we are doing should not be allowed to send oysters into our state if they are not following the icing and the whole thing. I have looked online and there are a few places that I looked at – they don't show anything yet – I even looked at Canada and I couldn't find anything where they had done it. It may just be I couldn't find anything current. I just wanted to be sure that oysters aren't sent to Maine that aren't being handled that same way, because it would really put us at a disadvantage. If you do annual classes, do I have to take a class in order to harvest my oysters, and another one as a certified dealer? I definitely don't want

to have to take two classes a year, whether it's online or not, I just...I forgot it this year on my LPAs – I'm getting away from the LPAs – I'm going to leases – but the one thing I hated about LPAs is coming to leases.

Written Comments Received by Email:

Lydia J. Treanor

Regarding Chapter 115 *Vibrio parahaemolyticus* Control Plan

February 10, 2024

My name is Lydia J. Treanor, and I was born and raised in rural Maine. I am interested in the proposed rulemaking regarding *Vibrio parahaemolyticus* because of my desire to keep local aquaculture industries economically and biologically healthy to benefit the people and communities in Maine. I am also interested in ensuring the proper safeguarding of marine resources, which are some of the State's most vital natural resources.

I am taking the opportunity in this comment to testify in full support of the proposed rulemaking for the Chapter 115 *Vibrio parahaemolyticus* Control Plan. Specifically, I am testifying about how the drafted harvesting restrictions and education initiatives in the proposed Control Plan are likely to be highly effective at reducing instances of illness in local coastal communities and beyond, while still protecting the interests of harvesters and encouraging the lively seafood harvesting culture that exists in coastal Maine.

One of the main risks of *Vibrio parahaemolyticus* in raw or undercooked oysters is that an infected oyster is undistinguishable from an uninfected oyster.¹ There is no different look, smell, or taste to an oyster infected with *Vibrio*.² As a result, nearly 80,000 people get vibriosis every year and 100 people die annually in the United States after ingesting the bacteria.³ These illnesses are most likely to occur from May to October when water temperatures are warmer.⁴

Managing the risk of *Vibrio parahaemolyticus* is critical to the oyster farming industry in Maine, especially considering that the annual oyster harvest typically yields around 3 million oysters.⁵ These oysters come from 150 farms throughout the state⁶ with the industry bringing in over \$10 million in 2021.⁷ Clearly, this industry is an important source of income and employment along the Maine coast. I believe that the proposed Control Plan effectively addresses and mitigates the risk of selling contaminated oysters and therefore also effectively protects the long-term economic interests of oyster harvesters by ensuring that the industry remains sustainable and prosperous despite warming water conditions and increased risk of *Vibrio*.

I also believe that the proposed Control Plan effectively utilizes the leading scientific research to maintain public health and safety. For example, the Washington State Department of Health relied on extensive scientific data and ultimately concluded that the best way to reduce the chance of illness is to reduce "opportunities for *Vibrio parahaemolyticus* growth after harvest, and restricting harvest when environmental conditions are ideal for *Vibrio parahaemolyticus* growth."⁸ The proposed Control Plan follows the same evidence-based science relied on in

Washington and imposes harvesting restrictions and time-to-temperature requirements during harvest periods, both proven methods of reducing the chance of illness for consumers.

Further, the Institute of Marine Sciences at the University of North Carolina at Chapel Hill published a study in 2015 detailing the most effective measures to manage the human health risks of *Vibrio*. The study acknowledged that harvest restrictions alone cannot eliminate the problem of illness from infected oysters. The study discusses the need for education and outreach programs, explaining that warnings of the risk for vibriosis have proved ineffective and have historically failed to reduce illness. The study concludes that desensitization to these warnings “can be reduced by educating shellfish growers and the shellfish consuming public.”⁹ The proposed Control Plan incorporates this guidance by imposing a requirement for mandatory *Vibrio* training for oyster harvesters and allowing municipalities to collect oysters for related training.

I fully support the proposed Chapter 115 *Vibrio parahaemolyticus* Control Plan because it incorporates the leading science into the updated rules, supporting public health and safety through reducing the chance of illness, while also promoting economic security for oyster harvesters. These benefits will in turn protect the precious marine resources in the State of Maine for all to enjoy.

Thank you for your time and consideration.

Very Respectfully,

Lydia J. Treanor

1 *Oysters and Vibriosis*, CENTER FOR DISEASES CONTROL AND PREVENTION, <https://www.cdc.gov/foodsafety/communication/oysters-and-vibriosis.html> (last visited Feb. 8, 2024).

2 *Id.*

3 *Id.*

4 *Id.*

5 *Maine Seafood Guide – Oysters*, THE UNIVERSITY OF MAINE,

[https://seagrant.umaine.edu/maine-seafoodguide/](https://seagrant.umaine.edu/maine-seafoodguide/oysters/)

[oysters/](https://seagrant.umaine.edu/maine-seafoodguide/oysters/) (last visited Feb. 8, 2024).

6 *Id.*

7 Jack Molmud, *Maine’s Oyster Industry Sees Record Sales as More Farmers Cash In*, NEWS CENTER MAINE (June

27, 2022), <https://www.newscentermaine.com/article/money/business/maine>.

8 *Vibrio Control Plan Rule Requirements*, WASHINGTON STATE DEPARTMENT OF HEALTH,

<https://doh.wa.gov/community-and-environment/shellfish/commercial-shellfish/vibrio-control-plan> (last visited Feb.

9, 2024).

9 Brett A. Froelich & Rachel T. Noble, *Vibrio Bacteria in Raw Oysters: Managing Risks to Human Health*, PHIL.

TRANS. R. SOC. B., Dec. 2015, at 2.

February 22, 2024

To: Deirdre Gilbert

I am an oyster lease holder in Muscongus Bay (MUSWHAR) and have a comment regarding proposed Vibrio regulation.

While it's clear that I will no longer be able to sell oysters from my home, could you please confirm that I will still be able to sell directly from my lease site per 6810-B(4) if the new rule passes?

I've developed a local clientele that visit the site to purchase directly and safely from my lease site waters and frankly, this revenue sustains the farm economically.

I would appreciate clarification.

Many thanks

Ray Konisky

Friendship Oyster Company

February 23, 2024

To Whom It May Concern:

We are writing in regards to the DMR Rulemaking process as it pertains to changes proposed for Chapter 115 Vibrio Control Plan. We are the owners and operators of Maine Ocean Farms LLC in Freeport, an aquaculture business focused on the cultivation of oysters. We have been in business for eight years and had market product for sale for six years. As our business has grown in scale, market product quantities have increased, and sales channels have expanded, we have always been striving to find the best practices and methods of growing, handling, harvesting and delivering our oysters. For the past four years we have undertaken and refined a process that has met or exceeded the temperature controls implemented for vibrio control not because it was required or even suggested as the best practice, but because this is how we produce and deliver the highest quality, consistent, and safe product to our wholesalers and direct-sales customers. We have embraced the benefits of using an ice slurry to initially drop the harvested oysters temperature and then packing product on ice in Xactics to hold the temperature for transport and delivery. It took a couple months to iron out the logistics, infrastructure requirements and the process but it is now one more part of our weekly routine and we would be happy to share what we have learned.

We are in full support of the transition to state wide Vibrio Control as I feel it is an important step in recognizing that both our temperatures and ecosystem conditions are changing, as well as our risk tolerance as an industry and society. None the less, some aspects of these proposed rule changes will impair our ability to conduct business, and we are concerned that the true operational implications of these fast-paced changes has not been fully contemplated or recognized.

The most acute change for our business will be the barring of home sales during the vibrio control season. There was a retail shift induced by the pandemic when the Governor's office effectively shut down all of our restaurant partners and distributors, as a result our direct to consumer sales channel was the only one we had left. Direct to consumer sales became an important aspect of our business operations and a key way for us to build good will, share information about Maine aquaculture as an industry and develop new relationships with the local community who as a result view our oysters as "their oyster, from their own back yard". Something they are proud of and are able to treat friends and family to who visit them, as locals who know where to get the freshest local seafood direct from the farmer, their neighbor who grew them just out there where those yellow buoys are. Consumers genuinely value the ability to buy product direct from the harvesting farmer, and it is a crucial aspect for farmers to derive the highest sales value for our product. On the financial side direct to consumer sales yield on average a 50% higher return than sales to a distributor or retailer. Building ongoing relationships with consumers who live locally lends itself to direct community support of and education about the aquaculture industry and appreciation to what products are grown close at hand. We are concerned that this portion of the rule change is overreaching in the way it will negatively impact our ability to conduct direct to consumer sales during a major portion of our seasonal operation. We are supportive of additional language and steps to lay out to best practices and mandated thresholds for the home sale process, but barring it completely is a dramatic and negative change that will undermine our ability to operate a viable small business and our ability to build strong ties to our coastal community.

While the potential barring of home sales was called out specifically in the proposed Vibrio Control rule changes, we are concerned that there is still uncertainty around other aspects of direct to consumer sales, and product sampling. As of the current proposed changes, could sales directly off a lease site still be conducted? Are there time constraints or temperature thresholds for conducting these direct to consumer sales directly off a lease site? As part of a paying tour of a lease, can oysters still be served and/or sold to passengers? Are there time constraints and temperature thresholds pertinent to this product sampled as part of a farm tour? We ask because we are acutely aware of the uncertainties and financial implications after the Vibrio outbreak that occurred in 2023. We have policies and procedures that we feel meet or exceed all of the best practices for sampling, harvesting, cooling, and serving product directly from the lease site as part of a farm tour. Without clarity however there is still room for other operators to adhere to lesser standards and increase the risk of adversely affecting all businesses operating in this capacity. We generate a critical part of our revenue from charter tours of the farm and without the ability to serve oyster samples as part of the experience we will likely not be able to continue to generate bookings for these tours which will have a considerable impact on our revenue.

As a business that has fully implemented an ice slurry process and iced coolers for all deliveries for the past four years, we have a good idea of the scale, cost, and impact these practices have. Beginning with the most crucial aspect, ice. To our knowledge there are only two commercial retailers of bulk ice in Maine, Vessel Services in Portland and Getchell Bros in Brewer. We are thankful to utilize Vessel Services, but the reality is that they routinely run out of ice. While our seemingly small 2000 lbs per week doesn't drain the availability on its own, vessels that easily take 20 tons at a time can quickly diminish the supply to a point it is unavailable. While we are

sure the market will eventually respond to the additional ice demand with additional suppliers and ready access in more locations, will that really happen by June 1 2024?

Not only does procuring ice at the right times for harvest days mean added logistics and travel time, but it adds cost, over \$150 per week for the ice itself. Add that alongside half Xactics at \$750 a piece, carrying about 1800 oysters and ice in the middle of the season and weighing over 400 lbs each. Suddenly you need a larger vehicle to transport even a moderate sales volume. Lifting those Xactics from your boat to your truck, never mind if you have a boat that will support carrying more than a couple, will require use of the crane at the municipal pier. Now suddenly every harvester needs to share usage of the crane, alongside all the lobstermen and seiners, adding more congestion to an already over taxed asset. Our point is that the ripple effect of cost, scale, and infrastructure burdens will ultimately drive small operators out of business and add an undue burden to the whole system for everyone as it is sorted out.

As a business that has had the foresight to incrementally add these infrastructure changes over the past 4 years, the expense and logistics are something we have already addressed. We are worried about the shared commodities and access points. The ice and the municipal piers being the choke points. Additional investment and planning on behalf of the state to help address these needs would seem appropriate when undertaking a rule change with this great an impact on the industry. Offering support to set up additional ice sources, build out or upgrade pier lifting capacities, and working with municipalities to address the growing need for commercial infrastructure. With a rule change that will have very direct implications to the bottom line of all businesses in the sector, it would seem appropriate to compensate with additional support.

We imagine many mid-size operators will expand to have dealer licenses and facilities in order to help streamline and ensure a smooth distribution chain. But this will once again squeeze even more overhead cost out of each individual oyster coming to market where margins are already tight and consumer food prices rising fast across the board.

In conclusion, instead of banning these sales we ask you to consider, allowing home sales to continue to be allowed as well as sales or sampling directly off of a Lease site or on a Oyster Farm Tour. Layout parameters or a best practices checklist for conducting these sales. Take a comprehensive look at the implications this rule will have on infrastructure including hoists and vessel weight capacities, access to limited resources such as Ice, the financial viability of small and mid-sized oyster farms without a direct sales channel and the ability to offer the unique experience of a farm tour. Please consider the potential diminished community support for aquaculture and oyster farming in general that could be inadvertently created by the loss of the ability to sell directly and to engage with our communities that share the shores and waters where our farms are sited, in such a personal and direct way.

Regards,
Willy Leathers & Eric Oransky
Co-owners and Founders, Maine Ocean Farms
Freeport, Maine

February 23, 2024

Dear Ms Gilbert,

My name is Christopher Sewall, I am the 3rd generation President of our family business Hermit Island Company, located in Small Point on the southern tip of the town of Phippsburg. Our company business includes a family tent campground and a lobster wharf which were started by my grandfather Sumner Sewall in the early 1950's. In addition to my role directing the family business, I have been growing oysters in the waters around Hermit Island for over 12 years and own and operate the Hermit Island Oyster Company. I have reviewed the proposed Chapter 115 Vibrio Control Plan and have the following questions and concerns.

The proposed regs state "Harvesters will not allow shellstock to deteriorate or decompose from exposure to warm ambient air temperatures (>60)". Yet under the listed definitions nowhere does the DMR define the meaning of "deteriorate or decompose". As oysters will necessarily be exposed in harvest to ambient temperatures over 60, how does DMR define "deteriorate or decompose" and how does that differ from the necessary exposure to these temperatures?

The proposed regulations will prohibit the sale of oysters from home. The concept that preventing sale of oysters from home will reduce the likelihood of Vibrio infections is akin to reducing traffic accidents by not letting people drive. Another analogy would be to reduce the the likelihood of gun injuries by prohibiting the sale of bullets. The months covered by this plan are peak tourist season and the best time for small producers to reach the most customers. According to the rule making fact sheet, the 2023 vibrio outbreak on Casco Bay was likely the result of inappropriate post harvest handling. It seems unfair that all growers should pay the price for the negligence of one. I have been successfully harvesting and selling oysters direct to customers since I started and by obeying currently existing law and best practices have not made anyone sick. If harvesters are not currently complying with the law and best practices, how does this rule change make any difference on the ground? It seems that grower and consumer education should be a priority. I believe that people growing food have a right to sell that food to the public. The producer has a responsibility to make sure that food is safe for the consumer and the consumer has the responsibility of storing and preparing that food in a safe manner. I don't see any reason that home sales should be discontinued. What is the difference between getting an oyster from a home refrigerator and getting an oyster from a store refrigerator? The net effect of this rule will be to limit the ability of small growers from selling their product.

The harvest restriction requiring immediate icing will require enormous amounts of ice along the Maine coast. As the DMR has extensive records of oyster harvests, how much ice has the DMR calculated to be needed for these harvests? And where will growers acquire this ice? During the past several summers we have had difficulty in maintaining stocks of ice for our camping customers. At times the entire Phippsburg peninsula was out of ice-restaurants, campgrounds and stores. Consolidation in the potable ice industry has meant that we can only get one company out of Sanford Maine to deliver ice to our business and Arctic Glacier has let us run out several times in the past 2 summers. I fear this requirement will create massive strain on the existing ice supply and make it difficult or impossible for small growers to obtain in a cost effective manner. This icing requirement could result in a massive increase in costs for small

growers who would have to travel potentially long distance and frequently in order to have the ice required for these proposed regulations. Why couldn't reusable cold packs or mechanical refrigeration provide for the lower temperatures desired? The increased use of fossil fuels required to obtain and transport this ice to our farms is contrary to the States goals of reducing global warming emissions.

Overall I fear these proposed regulations will have the impact of forcing small farmers out of business by making it more difficult to sell their product to customers and greatly increasing the cost of getting that product to customers. Nothing in these regulations increases enforcement of any rules and it is my contention that if already existing guidelines, laws, and best practices were followed and enforced, the State could achieve its goal of limiting the likelihood of vibrio infection from oysters harvested in Maine waters.

Sincerely,

Christopher Sewall
PO Box 29
Phippsburg, Maine 04562

I oppose this .I make a living off of selling g clams to my local community wich is the only way people can get truly fresh product..(shellfish..) how can you give all this power to the dealer who controls the buying amount and the selling amount with no.regulations? .dmr has us tag our.product that the dealer can hold on to [for.no](#) specific time and then [sell.to](#) a restraint or broker with my tag in them ...that could take weekssomeone gets sick and it's the diggers fault..in ten years no one has ever been sick from my kooler from my farmstand ..how can you say in the paper quoted from. Dmr..that they're trying to prevent the product from being bought privately then left on a restraint floor ..makes no sense??? Even d.m.r. Brent chase had no words for this.i ask him.showed him..sounds like inspectors aren't doing there job..seems like a cover up for the years of mis management there are so many better solutions but because you dont.live the life you don't know...clams are 1.50 a pound..everything in life is.more expensive but clams unless you buy them.from a.dealer for 10 ..15 bucks a pound..I sell mine to neighbors for 3\$ fresh after tide..I know the laws ..where to dig..and more cause I'm a 3rd generation digger...changes need to be made yes to the whole infrastructure..and letting dealers pay less than minimum wage is a crime..now they're gonna control cost too...that's a .monopoly..how can you group 5 different species that live in different depths of title zone..against wheres the research..why do you need more clam wardens if your trying to make all the areas recreational digging..why are you taking away our rights to survive and how can you be bias..there's so much more to this how can you be bias when you don't know or have the facts? Where's the research ?..can someone please call me and explain this to me..207.322.0242.lisc # 34361s thank you looking forward to hear from you I just don't get it jody stahre..

DMR Response to Comments:

Prohibition on Home Sales

The ban on sales from harvester's and grower's homes is proposed to be in effect during the Vibrio control season from June 1st through October 15th. This ban is for the species defined in Chapter 115, American oysters and European oysters statewide and hard clams from the upper New Meadows River, and not for any other species. Outside of the Vibrio control season, home sales would still be allowed for American oysters and European oysters statewide and hard clams from the upper New Meadows River. Sales of American oysters and European oysters statewide and hard clams from the upper New Meadows River directly from aquaculture lease sites will still be permitted during the Vibrio control season.

Home sales are proposed to be banned because of the enforcement limitations of inspecting and regulating activities at an individual's private home and because a customer could not reasonably assess whether Vibrio controls have been followed. Following the Vibrio outbreak in the summer of 2023 that resulted in 6-8 people becoming sick and a growing area closure that lasted 10 weeks, DMR feels the risk to consumer health and the viability of the industry is too high to continue allowing unregulated home sales. However, DMR is sensitive to this loss in opportunity for harvesters and is investigating ways to provide a different opportunity for direct retail sales. As indicated previously, retail sales at aquaculture lease sites are still permitted under the proposed regulations.

A point of clarification is that home sales have been banned in various parts of the state since Vibrio Control regulations were first implemented. The proposed regulation expands these controls to apply to the whole state for oysters. The statement "if already existing guidelines, laws, and best practices were followed and enforced, the State could achieve its goal of limiting the likelihood of vibrio infection from oysters harvested in Maine waters." is inconsistent because there are currently no Vibrio control rules for the entire state and by definition, guidelines and best practices cannot be enforced.

Annual Training Requirements

The training requirement must be completed once a year, regardless of the capacity in which the individual completes the training (e.g. if an individual is a harvester and also a dealer they can indicate they are completing the training for both categories). Because Vibrio controls are new to most of the state, the annual training is important to educate the industry and generate compliance with the regulations in order to prevent illnesses. Vibrio Control Regulations have been updated frequently over the past number of years and the annual training requirement provides an opportunity to directly inform the industry of these changes.

Practices in Other States

With regard to the comment on other states and countries following the same Vibrio regulations, the National Shellfish Sanitation Program allows member states and conforming countries to develop and implement their own Vibrio Controls specific to their circumstances (e.g. warmest time of the year, specific products harvested etc.). All required Vibrio Control Plans are

evaluated for effectiveness and compliance with the NSSP by the US Food and Drug Administration.

Costs of Compliance

DMR acknowledges these regulatory changes will potentially result in additional costs to their operations and there may initially be infrastructure limitations on the availability of ice. However, following the outbreak in the summer of 2023 and an increase in sporadic cases of *Vibrio* illness in Maine, it is clear these measures are important to ensure consumer safety.

The concern over the availability of ice questions why ice packs can't be used. The regulations only specify that ice made from a potable water source must be used and adequate ice must be used to cool product. If a harvester uses an ice slurry to rapidly cool product they can put the cold shellfish into a cooler with reusable ice packs to maintain temperature.

Rule-Making Fact Sheet

(5 M.R.S., §8057-A)

AGENCY: Department of Marine Resources

NAME, ADDRESS, PHONE NUMBER OF AGENCY CONTACT PERSON:

Deirdre Gilbert, Department of Marine Resources, 21 State House Station, Augusta, Maine 04333-0021 Telephone: (207) 624-6550; web address: <http://www.maine.gov/dmr/rulemaking/>

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.