SHELLFISH ADVISORY PANEL
3PM
Tuesday, November 15, 2022
John C. Curtis Public Library
534 Hanover Street
Hanover, MA 02339

1. Introductions and Remarks (3:00-3:15)
    a. Director's Remarks
    b. Review of November 15, 2022 Business Meeting Agenda
    c. Review and Approval of May 20, 2022 Draft Business Meeting Minutes
2. Special Review Procedure for MEPA Review of Aquaculture Siting (3:15-3:30)
3. Report on Bulk Tagging Sub-Committee (3:30–3:45)
4. ISSC Update (3:45-4:15)
    a. 2023 Biennial Meeting – March 18 – March 23 in Barton Rouge, LA
    b. Proposals and Committee Work
5. FDA 2022 PEER Review Update (4:15-5:00)
    a. Growing Area Classification
    b. VP Risk Assessment and Risk Management Evaluation
6. Wastewater Treatment Plant Modeling and MSC Study Update (5:00-5:15)
7. Surf Clam Management Update (5:15-5:30)
8. Dinner Break (5:30-6:00)
9. Other Business
    a. Panel Member Comments
    b. Public Comments
    c. Adjourn

SHELLFISH ADVISORY PANEL
May 20, 2022
Held Virtually via Zoom

In attendance:
Shellfish Advisory Panel: Bill Doyle; Renee Gagne; Seth Garfield; Michael Moore; Todd Callaghan; Lisa Rhodes; Michael DeVasto; Alex Hay; Shannon Emmett (on behalf of Mindy Domb); Josh Reitsma; Sean Bowen; Ron Bergstrom; Stephen Kirk; and Allen Rencurrel. *Absent:* Mike Trupiano; Amy Croteau; Bob Colby; Dale Leavitt; Jim Abbott; John Lebeaux; Jim Peters; and Rebecca Rausch

Division of Marine Fisheries: Jared Silva; Jeff Kennedy; Thomas Shields; Chrissy Petitpas; Mark Rousseau; and Matt Camisa

Massachusetts Environmental Policy Act Office: Tori Kim; and Paige Czepiga

NOAA: Chris Schillaci

Members of the Public: Helen Miranda Wilson; Mark Begley; Beth Gibbons; Matt Haney; Chloe Starr; Hillary Greenberg; Rebecca; David Slack; Suzanne Phillips; Beth Gibbons; Heinz Proft; Scott Soares; Danny Badger; Matt Haney; Rebecca Taylor; and Pat

INTRODUCTIONS AND ANNOUNCEMENTS

Jeff Kennedy called the May 20, 2022 Shellfish Advisory Panel ("SAP") Business Meeting to order. He stated Dan has asked him to chair the meeting as he had a conflict, and Jared Silva will be running the technical portion of the meeting.

Jeff then explained the need for this SAP meeting highlighting the SRP for MEPA as the main topic. Jeff then asked Jared Silva to take attendance.

REVIEW AND APPROVAL OF MAY 20, 2022 BUSINESS MEETING AGENDA

Jeff welcomed any questions or comments regarding the business agenda. There were no requested amendments to the agenda.

REVIEW AND APPROVAL OF MARCH 1, 2022 DRAFT BUSINESS MEETING MINUTES

Jeff asked the Panel for any changes or input regarding the March 1, 2022 SAP meeting minutes. No amendments were made to the minutes.

Chairman Kennedy asked for a motion to approve May 20, 2022 SAP business meeting agenda. Todd Callaghan made the motion to approve the May 20, 2022 business meeting agenda. Seth Garfield seconded the motion. A roll call vote was

taken and the motion passed unanimously 11-0-3 with Alex Hay, Mindy Domb, and Renee Gagne abstaining.

CHAIRMAN'S COMMENTS

Jeff Kennedy thanked everyone for their attendance and moved on to the joint presentation with MEPA regarding the Special Review Procedure (SRP) for environmental review of shellfish aquaculture projects.

Massachusetts Environmental Policy Act (MEPA) Special Review Procedure (SRP) for Environmental Review of Shellfish Aquaculture Projects

Jeff Kennedy provided the panel with a presentation regarding MEPA and the SRP process. Jeff asked Chris Schillaci from NOAA to give an overview.

Origin and History of DMF Request to MEPA for SRP
Chris Schillaci provided the Panel with an aquaculture overview presentation. Chris Schillaci gave some background on the number of acres of aquaculture sites in MA as well as the average acreage per site. Chris then moved on to discuss some challenges facing growers. Some of the challenges included: small growers are required to navigate web of federal, state, and local permitting requirements; permit agencies differ in how impacts are calculated, and whether they require permitting at all – requirements vary across municipalities; the majority of small projects have predictable and minimal impacts on environmental resource areas .

He then moved on to describe the impacts of these challenges and the need to provide clear guidance to growers. Aquaculture is subject to MEPA, and Chris explained that the SRP will allow the state to look at the impacts of the different gear used in aquaculture as a whole. Chris then turned the floor over to Chrissy Petitpas who provided more in-depth background.

Existing Permitting Process and Challenges
Chrissy stated that shellfish aquaculture may be licensed to plant and grow shellfish, place shellfish in or under protective devices, harvest and take legal shellfish, plant cultch for the purpose of catching shellfish seed, and grow shellfish by means of racks, rafts, or floats. She went on to describe the required permits which includes a municipal license; DMF section 57 certification, and a DMF propagation permit in addition to potentially an order of conditions from local conservation commissions; MEPA review; Natural Heritage and Endangered Species Program (NHESP) review; MassDEP c.91/Water Quality Certification (WQC); US Army Corps of Engineers SVN, General or Individual permit; and federal consistency review by Coastal Zone Management. Chrissy pointed out that these are not consistent among different municipalities.

Chrissy turned the floor over to Tori Kim and Paige Czepiga to discuss the current MEPA process and the proposed SRP.

Paige Czepiga reviewed the purpose of MEPA (MA Environmental Policy Act), it applies to projects requiring agency action which includes state permitting. It requires assessment of environmental impacts, review of alternatives, and development of mitigation measures. The MEPA agency must certify that all feasible measures to avoid or minimize environmental damage will be taken before taking action (i.e. issuing permits).

Paige then went into detail regarding when a project requires agency action. Usually a project requires an agency action when both a project is undertaken by agency (usually state agency), a project requires from an agency a permit (such as the DMF Sec 57 certification for aquaculture) or financial assistant or land transfer AND a project meets or exceeds a MEPA review threshold such as land, rare species, wetlands, water, wastewater, transportation, energy, air, solid/hazardous waste, historical/archaeological resources.

Paige noted that MEPA review consists of filing an Environmental Notification Form (ENF) and possibly a lengthier Environmental Impact Report (EIR) process. Paige then moved on to discuss the current MEPA Process.

Current MEPA Process
Paige described several examples of MEPA review, one example was thresholds such as alteration of > ½ acre of wetlands (including coastal beach, land underwater. She then went over agency actions applicable to shellfish aquaculture such as: DMF Section 57 Certification, Chapter 91 license/permit, 401 water quality certification, Superseding Order of Conditions, and a Conservation and Management permit (CMP) for NHESP.

Paige discussed new requirements effective Jan. 1, 2022. These are as follows: Any project within a 'designated geographic area' of Environmental Justice (EJ) populations (typically 1 mile) must undertake the EIR process. The project may seek to expedite review by requesting a 'single EIR' or a 'Rollover EIR'; however a minimum of two review periods each is required. Another new requirement is that all projects must conduct prefiling outreach to EJ populations. Additionally, if the applicant is seeking an expedited review, 45-day advance notification must be provided to a list of local organizations.

Description of SRP for Shellfish Aquaculture Projects
Paige Czepiga then outlined the SRP and how it will modify the MEPA review process. Paige stated that the secretary has the authority to create special review procedures (SRP) for certain categories of projects for which typical review process may not be warranted. Paige stated that the SRP serves the purposed of MEPA by:

- Providing meaningful opportunities for public review
- Analysis of alternatives
- Consideration of cumulative environmental impacts

Paige then stated that the SRP may provide the following: review of documents other than ENFs and EIRs, and shortened or extended review periods. Paige stated that SRP can increase the efficiency of MEPA review and reduce the administrative burden.

Paige then highlighted the proposed SRP for shellfish aquaculture. No MEPA review would be required for projects less than two acres. Projects equal to or greater than 2 acres and less than ten acres would need to submit a copy of (new) DMF Aquaculture Description Form and conditional certification letter to MEPA. The form will include cumulative impacts table from DMF, and EJ supplement if the project is within one mile of an EJ population. If the project is greater than or equal to ten acres the project would not be subject to the SRP and must follow normal MEPA procedures. Paige concluded her comments on the proposed SRP by stating that the SRP is intended to streamline review for small projects, while allowing for review of cumulative impacts. She added that this is limited to projects requiring only DMF Sec 57 certification. If other state agency permits are required, the project must follow normal MEPA procedures.

Paige stated that the SRP is proposed as a one-year pilot to streamline MEPA review for simple projects and to begin to apply consistency in permitting approaches. The one-year program would not apply to projects that need other state permits such as cultch projects, placement of permanent, non-seasonal gear, and kelp or other aquaculture activities not associated with 'class three/type one' permits issued by DMF.

Paige discussed the timetable and next steps with the SAP. Some dates that were of note included August or September of this year, MEPA hopes to have the final SRP published and effective. In July and August of 2023, DMF and MEPA will consider whether to extend or modify the SRP after the one-year pilot. Paige thanked everyone for their attendance and welcomed a discussion from the Panel.

SAP Discussion

Steve Kirk asked about how the cumulative impact assessment is reviewed by the MEPA office. Paige stated MEPA looked at the number of projects in the same embayment. Paige stated MEPA is open to discussion of the (*negative*) impacts as well as benefits of the projects within the cumulative impact assessment. MEPA is not necessarily a permitting process but rather an environmental review and disclosure process.

Dale Leavitt asked how the SAP will be of help to MEPA, and what they are looking for from the Panel. Tori Kim explained that they would like feedback from industry on the appropriateness of the SRP and any comments on the concept of the SRP. Tori Kim also added that MEPA is looking at this as a pilot and is looking for it to become a permanent solution that would apply to other permits. She anticipated bringing the long-term solutions back to the Panel at some point in the future after the pilot program has come to an end.

Sean Bowen asked about the spatial thresholds and how it would apply if a farmer were to expand their growing area. Tori Kim gave Sean an in-depth response, and she stated that each additional expansion would likely be considered a new project.

Alex Hay asked what MEPA sees the permitting process looking like in the future. Tori Kim described several different options including regulatory review processes.

Mike DeVasto stated he is currently going through the MEPA process, and expressed frustration over the length of how long the process has taken. He then asked Tori Kim about the spatial thresholds. Tori Kim stated there has been a backlog and they are working through the different requests. She then provided Mike DeVasto with insight as to how they determined the spatial thresholds. Mike DeVasto suggested using language for accepted practices for aquaculture in the event that new aquaculture gear is developed for use.

Chris Schillaci thanked MEPA for taking on the pilot program. Chris stated there are projects that could potentially support an expansion to this program and asked whether MEPA would be interested in considering these projects for an expansion of the pilot program. Paige stated that this could be possible with the support of partner agencies in the future. Tori Kim stated that currently they are more focused on smaller projects that they know have minimal impacts but are open to expansion.

Josh Reitsma stated there are best management practices in place in MA. He asked MEPA which impacts a prospective grower would need to put down. Tori Kim stated the expectation of the new grower would be to fill out the new form and would work with DMF to determine the cumulative impacts.

Dale Leavitt asked if the form DMF is developing is meant to be a common application for all agencies and if the SAP would be helping create the form. Chrissy Petitpas stated the other agencies have their own application processes, but the aquaculture description form would be a supplement to the municipal application form. DMF would ask municipalities to use the form as supplemental to their applications. Dale advocated for having each agency use the same form for ease. Chrissy stated this could be considered provided there is sufficient interagency interest in the future.

There were no further questions from the Panel, Jeff Kennedy welcomed any comments from the Panel members.

OTHER BUSINESS

Panel Member Comments

Allen Rencurrel requested two proposals to be added to the next SAP meeting, one is to plant surf clam seed in state waters, and the second would be to re-open Hatches Harbor off Provincetown for surf clammers. Jared stated he will follow-up with him after the meeting and Dan McKiernan intends to add them to the next SAP meeting.

Lisa Rhodes thanked MEPA for their efforts.

Renee Gagne stated Paul Bagnall asked if the SAP could weigh-in at the next meeting on the release of radioactive wastewater by Plymouth's Pilgrim nuclear power station into CCB.

Seth Garfield agreed with Renee that the issue should be discussed at the next meeting. He also would like to see a discussion on icing rules and regulations for MA, and the timing of getting logbooks to growers added to the next SAP meeting agenda. Jeff Kennedy stated that DMF is willing to have those discussions and addressing these issues at the next SAP meeting would be a good next step.

PUBLIC COMMENTS

Helen Miranda Wilson requested a list of participants who are in attendance at this Zoom meeting, as well as a link to the recording. Jared explained that due to the limitations of Zoom a list of participants is not available during the call, but he can send a list of participants after the meeting ends, a list will also be present in the minutes by the next meeting. He stated the link will be available on DMF's Youtube channel.

ADJOURNMENT

Jeff Kennedy asked for a motion to adjourn the Shellfish Advisory Panel meeting. **Mike Devasto made a motion to adjourn. Todd Callaghan seconded the motion. The motion was approved by unanimous consent.**

MEETING DOCUMENTS

- May 20, 2022 SAP Business Meeting Agenda
- March 1, 2022 SAP Draft Business Meeting Minutes

UPCOMING MEETINGS

The Commonwealth of Massachusetts
Division of Marine Fisheries

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CHARLES D. BAKER, Governor | KARYN E. POLITO, Lt. Governor | BETHANY A. CARD, Secretary | RONALD S. AMIDON, Commissioner | DANIEL J. MCKIERNAN, Director

Memorandum

TO: Dan McKiernan, Director
Jeff Kennedy, Shellfish Program Leader
FROM: Tom Shields, Shellfish Policy Analyst
DATE: August 23, 2022
SUBJECT: Shellfish Advisory Panel Bulk Tagging Subcommittee

Background

At the November 18, 2021, and March 1, 2022, DMF Shellfish Advisory Panel (SAP) meetings Dan stated his intentions to form three subcommittees to work on priority issues. The first will investigate the bulk tagging of shellfish by harvesters; the second will address municipal shellfish aquaculture license site transfer rules; and the third will investigate the impact of Section 208 of the Clean Waters Act (208 Plan) on the commercial oyster industry on Cape Cod. He stated his interest in convening the first subcommittee before the fall 2022 SAP business meeting, which most likely will occur in October.

It was decided to start with the bulk tagging subcommittee before undertaking the more complicated tasks required of the other two subcommittees. DMF staff assigned to the subcommittee will produce a summary or work product (e.g., memo, white paper) for the full SAP to deliberate at a future meeting. From there and depending on the situation, additional public scoping and public hearings may occur.

Bulk Tagging Subcommittee Members

We envision the subcommittee will consist of eight SAP members representing a range of stakeholders and regulators. Massachusetts Environmental Police (MEP) was also invited to participate in meetings of the subcommittee.

At the November 18, 2021 SAP meeting, members were asked to provide a list of their three top priorities SAP should address. Three of the 12-panel members who responded included bulk tagging as a top priority, with all three invited as members to the subcommittee. Below is a complete list of individuals invited to be on the SAP bulk tagging subcommittee.

SAP Bulk Tagging Subcommittee Members	
Name	**Affiliation**
Alex Hay	Wellfleet Shellfish Company
Amy Croteau	Barnstable Shellfish Constable
Bill Doyle	MFAC; Plymouth Rock Oyster Growers
Michael DeVasto	Field Point Oyster Farm
Seth Garfield	Cuttyhunk Shellfish & MAA President
Sean Bowen	MA DAR
Dale Leavitt	Blue Stream Shellfish & MAA Vice President
Michael Moore	MA DPH

Based on internal DMF deliberations and comments by industry participants at past Shellfish Advisory Panel meetings, I recommend the bulk tagging subcommittee take on the following responsibilities:

Subcommittee Charge: Explore options to expand the existing pilot bulk tagging program currently in place for shellfish aquaculturists who are DMF permitted growers and wholesale dealers acting as the primary buyer (original dealer) for their own cultured product.

1. Review existing regulations and DMF policy regarding issuance of LOAs to shellfish grower/dealers under the existing pilot bulk tagging program.
2. Investigate options for expanding the pilot bulk tagging program.
    a. Investigations should include input from DMF, DPH, MEP, oyster growers and wholesale dealers.
    b. Identify critical issues that may hamper implementation of trace back and recalls of contaminated shellfish resulting from an industry-wide bulk tagging program.
    c. Consider including bulk tagging of wild harvested shellfish.
3. Develop a review document ("white paper") describing both existing pilot program bulk tagging practices by grower/dealers and possible methods to expand bulk tagging to all permitted shellfish harvesters.

Supporting Documents and Information

DMF staff will collect and distribute DMF documents and other applicable information to support subcommittee deliberations, including, but not limited to:

1. Summary of regulations and DMF policy pertaining to the existing pilot bulk tagging program.
2. Review of acceptable harvester shellstock bulk tagging practices as defined in the NSSP Model Ordinance (2019 Version).
3. Compile existing historical documents and memos pertaining to past DMF and DPH deliberations regarding possible expansion of the pilot bulk tagging program.
4. Conduct a survey of other major oyster-producing state shellfish authorities regarding accepted bulk tagging practices utilized by harvesters. Survey questions will be developed and reviewed internally by DMF prior to initiating the survey. Survey results will be compiled and made available to the subcommittee.

Next steps

I emailed all subcommittee members inviting them to join the bulk tagging subcommittee. Once I get a response from everyone, I will send out a Doodle Poll to select a date and time for the first subcommittee meeting, hopefully in September. In the meantime, I will begin compiling the documents and information outlined above.

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September 9, 2022

CERTIFICATE OF THE SECRETARY OF ENERGY AND ENVIRONMENTAL AFFAIRS
ESTABLISHING A SPECIAL REVIEW PROCEDURE

PROJECT NAME:	Shellfish Aquaculture
PROJECT MUNICIPALITY:	Statewide
PROJECT WATERSHED:	Statewide
EEA NUMBER:	16583
PROJECT PROPONENT:	Division of Marine Fisheries
DATE NOTICED IN MONITOR:	August 10, 2022

Pursuant to the Massachusetts Environmental Policy Act (MEPA; M.G.L. c. 30, ss. 61-62L) and Section 11.09 of the MEPA regulations (301 CMR 11.00), I hereby establish a Special Review Procedure (SRP) to guide MEPA review of shellfish aquaculture projects proposed on sites licensed by municipalities and whose operations are permitted by the Division of Marine Fisheries (DMF).

The draft SRP was published in the Environmental Monitor on August 10, 2022 for a 20-day public review and comment period. I received 6 comments, including from the Provincetown Shellfish Department, Wellfleet Shellfish Constable, and several nonprofit organizations including MassAudubon, Massachusetts Bays, and The Nature Conservancy. Comments are generally supportive of the effort to streamline regulatory review for smaller, less impactful aquaculture projects, but emphasize the importance of considering the cumulative impacts of multiple operations sited in close proximity to one another. Comments also request that the scope and scale of the SRP be broadened to provide for a review of best management practices for aquaculture activities as a whole. As noted below, this SRP is proposed as a 1-year pilot to create a consistent review procedure for shellfish aquaculture projects, while allowing for reporting of cumulative impacts of projects located within the same waterbody. Participating Agencies will use the data collected during the 1-year pilot period to consider a broader permitting framework and associated MEPA reviews for aquaculture activities as a whole.

Background

On August 16, 2018, the DMF requested that the Secretary of Energy and Environmental Affairs (EEA) create a Special Review Procedure (SRP) (the "2018 DMF request") for shellfish aquaculture projects in the Commonwealth. As requested by DMF, notice of the request was published in the September 5, 2018 *Environmental Monitor*, which commenced a 20-day public comment period. I received comments on the 2018 DMF request from state agencies, regional planning commissions, environmental groups, and organizations working in support of the marine aquaculture industry. All comment letters expressed support for the request to establish an SRP. While a draft SRP was not published with the 2018 DMF request, the request letter indicated that the SRP would facilitate the development of a state-wide *Massachusetts Aquaculture Permitting Plan (MAPP)* that would support both private and municipal aquaculture activities. The DMF proposed to work with partner EEA agencies and a Citizen's Advisory Committee (CAC) to develop environmental and public use standards that would be incorporated into the MAPP. The scope of the MAPP was envisioned to be broad and include shellfish propagation and restoration projects, and as warranted, other activities such as macroalgae and finfish culture. The MAPP would then allow for streamlined MEPA reviews of projects satisfying the standards and best practices set forth in the MAPP.

Since the publication of the 2018 DMF request, DMF and partner EEA agencies have continued to convene to discuss the SRP request. DMF also launched a website[1] to provide permitting guidance for Massachusetts aquaculture projects. However, given the large scope and scale of the SRP as originally contemplated and the lack of best management practices for newly emerging aquaculture activities, DMF, in consultation with EEA agencies, has requested that the Secretary establish a more focused SRP to streamline review of smaller shellfish aquaculture projects, while EEA agencies continue to consider a broader permitting framework for aquaculture activities. As noted, comments received on this SRP reiterate a desire to develop a broader permitting framework and associated MEPA review that would result in identification of best management practices for the industry. I am establishing this SRP as a 1-year pilot and anticipate that data collected on shellfish aquaculture projects will be used by Participating Agencies in consideration of this broader effort.

Purpose of the SRP

DMF has requested that the Secretary establish this SRP pursuant to 301 CMR 11.09(4)(a) and (e). DMF engages in the certification of municipal licensing and permitting of shellfish aquaculture, along with various other state, local and federal agencies including the Massachusetts Department of Environmental Protection (MassDEP), the Natural Heritage and Endangered Species Program (NHESP), U.S. Army Corp of Engineers (USACE), and local Conservation Commissions. This SRP is proposed only for aquaculture activities associated with "Class 3 / Type 1" permits issued by DMF under 322 CMR 7.01(4)(c) and 322 CMR 15.04(1)(a)3. and 15.04(1)(b)1. ("Authorizes an open water system with minimal structures and no feeding" for "Shellfish").

Under M.G.L. c. 130, § 57, a city or town, after public notice and hearing, may grant a shellfish aquaculture license to any person to undertake shellfish aquaculture activities at all times of the year in, upon, or from a specific portion of coastal waters of the Commonwealth, of tidal flats or land under coastal waters. The license may authorize the following activities: (1) to plant and grow shellfish,

[1] https://www.massaquaculturepermitting.org

bottom/off bottom culture; (2) to place shellfish in or under protective devices affixed directly to the tidal flats or land under coastal waters, such as boxes, trays, pens, bags, or nets; (3) to harvest and take legal shellfish; (4) to plant cultch for the purpose of catching shellfish seed; and (5) to grow shellfish by means of racks, rafts or floats. The city or town may issue the license only after the DMF director certifies that "issuance of a shellfish aquaculture license and operation thereunder will cause no substantial adverse effect on the shellfish or other natural resources of the city or town." Failure of the director to so certify is deemed a denial of the shellfish aquaculture license. Shellfish aquaculture licenses issued pursuant to M.G.L. c. 130, § 57 are subject to rules and regulations promulgated by DMF, and may be conditioned by DMF as the director deems necessary and appropriate.

DMF certifications under M.G.L. c. 130, § 57 ("Section 57 Certifications") are deemed to be an "Agency Action" for purposes of MEPA review because they constitute a "permit, license, certificate, variance, approval, or other entitlement for use, granted by an Agency for or by reason of a Project." 301 CMR 11.02 (definition of "Permit"). Specifically, they constitute, together with the municipal license, an "approval" and "entitlement for use" for a specific portion of coastal waters for purposes of carrying out shellfish aquaculture; failure of DMF to issue the certification is deemed a denial of the shellfish aquaculture license. Most aquaculture sites range from 0.5 to 2 acres in size, and utilize gear (cages or tents) that are removed seasonally and result in minimal, if any, permanent impact to land under coastal waters. Because these types of operations are expected to have minimal adverse effects on protected areas and resources, state authorizations are often limited to DMF's Section 57 Certification and shellfish propagation permit. Projects that have the potential to result in greater or more permanent impacts, such as the placement of cultch directly on the ocean bottom and larger scale private aquaculture sites, often require additional state authorizations, including a M.G.L. c. 91 License and/or 401 Water Quality Certification (WQC) from MassDEP and, if federal permitting is required, a federal consistency determination from the Massachusetts Coastal Zone Management (CZM) office. If the site is located in mapped rare species habitat, it also requires additional consultation and/or permitting through NHESP.

This SRP is intended to increase the efficiency of MEPA reviews for aquaculture projects that require a DMF Section 57 Certification, but for which no other Agency Action independently triggers the need for MEPA review. For these smaller projects, with predictable and minimal individual impacts, DMF seeks an alternative, more efficient, MEPA review process. This SRP also seeks to ensure that the cumulative impacts of multiple projects proceeding in a similar time frame within the same embayment, including potential impacts to wetlands, eelgrass, rare species habitat, and navigable waters, can be reviewed through MEPA in coordination with Participating Agencies. This SRP shall be implemented as a 1-year pilot, and shall be modified as appropriate after such period.

To facilitate MEPA review in accordance with this SRP, DMF has developed an Aquaculture Description Form (the "DMF Aquaculture Description Form"), to be submitted by the project proponent when requesting a municipal license and associated Section 57 Certification, for purposes of disclosing site-specific information about the proposed aquaculture activities, gear types, potential environmental impacts, and cumulative impacts when considering other similar activities proposed in the same embayment during a similar time frame. The DMF Aquaculture Description Form will also be used to determine whether the project is subject to the size thresholds established under this SRP and/or may require Agency Actions other than the Section 57 Certification such that this SRP is not applicable. The

form will solicit information related to the project's environmental impacts and benefits relative to Environmental Justice (EJ) populations.

SPECIAL REVIEW PROCEDURE

To effectuate the purposes set forth above, I hereby establish this SRP to guide MEPA review of shellfish aquaculture projects authorized by DMF through a Section 57 Certification and a Class 3 / Type 1 propagation permit under 322 CMR 7.00 and 15.00. I find that this SRP serves the purposes of MEPA, including providing meaningful opportunities for public review, analysis of alternatives, and consideration of cumulative environmental impacts. The acreage of the entire project site will be considered for determining the applicability of the categories outlined below.

Project Sites of 10 or More Acres (≥ 10 acres)

Any shellfish aquaculture sites of 10 or more acres will not be subject to this SRP, and will be required to follow normal MEPA procedures. In most cases, these projects will trigger the 10 acre (EIR) threshold for alteration of "any other wetlands" under 301 CMR 11.04(3)(a)1.b.

Projects Sites of Greater than 2 acres but Under 10 Acres (> 2 acres but <10 acres)

Shellfish aquaculture projects in this size range that require a DMF Section 57 Certification, but no other Agency Actions, are eligible for the MEPA review procedures as described in this SRP. Shellfish aquaculture projects in this size range that require another Agency Action (in addition to DMF's Section 57 Certification) are not eligible for the MEPA review procedures described in this SRP and must undergo normal MEPA procedures.

If no other Agency Action has been identified for the project other than the DMF Section 57 Certification, projects that are greater than 2 acres but under 10 acres in size shall be permitted to file a copy of the DMF Aquaculture Description Form and DMF's conditional certification letter (the "MEPA Aquaculture Filing") to the MEPA Office in lieu of filing an Environmental Notification Form (ENF). The DMF Aquaculture Description Form shall attach a cumulative impacts summary, described in Part IV below. The MEPA Aquaculture Filing shall be published in the Environmental Monitor for a 20-day comment period, and the Secretary shall issue a Certificate within 10 days thereafter determining whether further review is warranted. If no review is required, the Certificate shall determine that the filing adequately and properly complies with MEPA and its implementing regulations. The Secretary may establish a standard format for such Certificates. If, based on comments received and consultation with Agencies, the Secretary determines that further review is warranted, the Secretary may issue a Scope for a Draft or Single Environmental Impact Report (EIR).

For any project located within 1 mile of an EJ population, the project proponent shall also include in the MEPA Aquaculture Filing, as an attachment to DMF Aquaculture Description Form, a supplement containing information describing the surrounding EJ populations and disclosing potential environmental impacts and benefits for such populations. The MEPA Office may provide a standard form to be used for this purpose, and such form shall be attached to the DMF Aquaculture Description Form. Projects subject to this SRP shall be exempt from the requirements of 301 CMR 11.05(4), and I

hereby find that the standards for a waiver under 301 CMR 11.11(1) are met in light of the burden posed to proponents and the minimal anticipated impacts of the projects that will be subject to this SRP. Notice of this SRP was provided on July 22, 2022 by DMF to a list of community-based organizations (CBOs) and tribes/indigenous organizations provided by the MEPA Office in consultation with the EEA EJ Director.

Projects Sites of 2 or Less Acres (≤ 2 acres)

If no Agency Action other than the Section 57 Certification independently triggers the need for MEPA review, projects that are 2 or less acres in size shall be exempt from any MEPA filing requirement. This provision does not exempt the project from other state permitting requirements that may apply to projects of any size, including a MassDEP c. 91 license, 401 WQC, and consultation and/or "take" permit from NHESP under the Massachusetts Endangered Species Act (MESA).[2]

Cumulative Impacts

Upon conditional certification of a license site, DMF shall coordinate with all project proponents to provide a cumulative impacts summary that addresses other similar aquaculture activities existing and/or proposed within the same embayment during a similar time frame to include with the DMF Aquaculture Description Form. Specifically, such information shall identify other existing and conditionally certified aquaculture sites, gear types, and acreage within the same embayment (contiguous waterbody) as the proposed site. DMF shall determine the appropriate form to record this information, and shall direct the proponent to include this information in the DMF Aquaculture Description Form. The Secretary's determination as to whether further MEPA review is required under Part II above shall consider the cumulative impacts of the proposed project in combination with other aquaculture projects proposed within the same embayment within a similar time frame.

Circulation Requirements

Each review document submitted under this SRP must be circulated in accordance with 301 CMR 11.16. Public notice under 301 CMR 11.15(1) is not required.

If a full ENF is required for any projects subject to Part I-IV above, the Proponent must comply with all requirements set forth in 301 CMR 11.00 and associated policies and protocols.

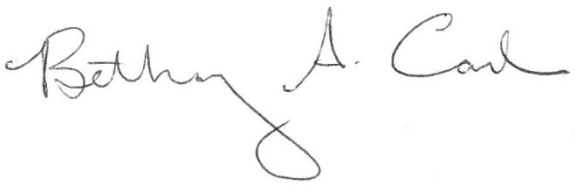
Term of SRP and Modification

This SRP shall expire one year after the date of signature, unless extended by agreement of the Parties. If DMF wishes to change any provision in this SRP, it may submit a letter requesting modification of the SRP. The Secretary will then review the request and issue an Amended SRP if appropriate.

[2]All projects located in designated priority habitat for state-listed species according to the Massachusetts Natural Heritage Atlas, must file with the Natural Heritage and Endangered Species Program (NHESP) pursuant to the MA Endangered Species Act (MESA), regardless of project size.

Conclusion

The signatures below indicate consent to the establishment of a Special Review Procedure and the provisions outlined in this SRP. In addition, DMF shall obtain, through the DMF Aquaculture Description Form, a signed acknowledgment and agreement to follow these SRP procedures by individual project proponents.



September 9, 2022
Date

Bethany A. Card, Secretary
Executive Office of Energy and Environmental Affairs

September 9, 2022
Date

Dan McKiernan
Division of Marine Fisheries

Comments received on the draft SRP:

08/18/2022	Michael Tlusty
08/29/2022	Provincetown Shellfish Department
08/30/2022	MassAudubon
08/30/2022	The Nature Conservancy
08/30/2022	Wellfleet Shellfish Constable
08/30/2022	Massachusetts Bays National Estuary Partnership

View Comment

Comment Details

EEA #/MEPA ID	First Name	Address Line 1	Organization
16583	Michael	21 Ashmont St	--
Comments Submit Date	**Last Name**	**Address Line 2**	**Affiliation Description**
8-18-2022	Tlusty	--	Individual
Certificate Action Date	**Phone**	**State**	**Status**
8-30-2022	--	MASSACHUSETTS	Opened
Reviewer	**Email**	**Zip Code**	
Page Czepiga (857)408-7049, page.czepiga@mass.gov	michael.t.011235@gmail.com	02176	

Comment Title or Subject

Topic: Aquaculture SRP

Comments

Segoe UI | 10 pt | Paragraph

The SRP is deficient in ensuring broader cumulative impacts do not occur. There should be a standard amount (5%) of eelgrass that can be impacted in an embayment, and this should occur across a longer time period rather than the "during a similar time frame" language in the SRP. Relying on self reporting by growers will likely underreport eel grass, and the term "may" is used as DMF inspection of sites. There should be formal, objective oversight of the total amount of habitat that is in each embayment.

Attachments

Update Status

Status

Accepted

SUBMIT

Share Comment

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View Comment

Comment Details

EEA #/MEPA ID
16583

Comments Submit Date
8-29-2022

Certificate Action Date
8-30-2022

Reviewer
Page Czepiga (857)408-7049, page.czepiga@mass.gov

First Name
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Email
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Address Line 1
--

Address Line 2
--

State
MASSACHUSETTS

Zip Code
02657

Organization
Provincetown Shellfish Dept

Affiliation Description
Municipality

Status
Opened

Comment Title or Subject

Topic: Segmentation of cumulative impact

Comments

Hello

For decades there has been a conflict with permitting aquaculture. It’s necessary for individuals, not municipalities, to go through the permitting process with MA Dmf so that food safety responsibility is placed on the individual. Environmentally, it’s necessary to look at the entire municipality’s aquaculture as one farming entity.

20 years ago Provincetown had 1 acre of aquaculture. As we started permitting with MADMF, we first had the individual grower go through a notice of intent with the town Conservation Commission. Our next round of permitting included closer to 10 individuals and acreages. After the third round, MEPA offices put a hold on new and transfer aquaculture for over a year. We had 38 acres of segmented permitting and if it had been individuals applying it would not have triggered environmental scrutiny.

I believe this is the problem at the origin and center of environmental permitting for aquaculture. The draft SRP sets up a scenario similar to the original problem. Permitting will continue in a segmented fashion, flying under the radar and eventually have cumulative impacts beyond MEPA office thresholds. We will be back to where we started.

This process needs to be an evaluation of each municipality as a single farming entity. The responsibility for this should be on the municipality. Section 4 of the SRP entitled: cumulative impacts is the only portion of the document dealing with the true issue. The proposed solution seems to fall in a subjective gray area. Ten individuals needing individual propagation permits (food safety and shellfish health) could put in 1 acre grants. If the secretary sees a cumulative affect triggering an ENF, the document would need to squarely make that the responsibility of the Town and not the tenth individual.

Basically individuals growing and harvesting shellfish have to be responsible for food safety. The municipality should be responsible for cumulative impact. The SRP is written in a way that doesn’t address long-standing issues. Thank you Steven Wisbauer

Provincetown Shellfish Constable

Attachments

Update Status

Status

Accepted

SUBMIT

Share Comment

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BACK TO SEARCH RESULTS

View Comment

Comment Details

EEA #/MEPA ID 16583	**First Name** Heidi	**Address Line 1** 208 South Great Road	**Organization** Mass Audubon
Comments Submit Date 8-30-2022	**Last Name** Ricci	**Address Line 2** --	**Affiliation Description** Individual
Certificate Action Date 8-30-2022	**Phone** --	**State** MASSACHUSETTS	**Status** Opened
Reviewer Page Czepiga (857)408-7049, page.czepiga@mass.gov	**Email** hricci@massaudubon.org	**Zip Code** 01773	

Comment Title or Subject

Topic: 16583 Shellfish Aquaculture proposed SRP

Comments

Segoe UI | 10 pt | Paragraph

On behalf of Mass Audubon, I submit the attached comments on the draft Special Review Procedure (SRP) for Shellfish Aquaculture proposed by the Division of Marine Fisheries (DMF). Mass Audubon supports the continued development of the aquaculture industry in Massachusetts, with appropriate geospatial planning and best management practices (BMPs). We recognize that some forms of aquaculture can have water quality benefits as well as economic value. We also support the use of shellfish restoration projects for Living Shorelines and other coastal resiliency projects, and recommend that regulatory streamlining be implemented to provide pathways for those projects to advance. This should include provisions allowing for no harvest sanctuaries for projects with goals primarily focused on habitat restoration, water quality, and climate resiliency. The current regulatory structure does not support those types of shellfish propagation projects.

As proposed, the SRP is likely to result in more than minimal individual and cumulative impacts. A Programmatic review that first establishes appropriate locations and BMPs would be a more appropriate vehicle for planning and streamlining permitting for new aquaculture. Mass Audubon has observed that intertidal and nearshore aquaculture projects are resulting in impacts including plastic debris, compaction, and displacement and disturbance of wildlife such as breeding and migrating coastal waterbirds. The potential impacts on other important habitat features such as eelgrass, including former eelgrass sites that may have the potential to re-grow if the site is not occupied by aquaculture, are unclear.

Mass Audubon recommends that instead of this SRP, DMF conduct a planning process and develop BMPs, consistent with the Massachusetts Ocean Management Plan. This should be conducted through an open and inclusive public planning process, which could utilize the Programmatic Review provisions in the MEPA regulations.

Mass Audubon would welcome the opportunity to engage with DMF and other organizations to provide further input.

Please see the attached letter for additional detailed comments.

Attachments

Aquaculture SRP Mass Audubon comments.pdf(null)

Update Status

Status: Opened — SUBMIT

Share Comment

SHARE WITH A REGISTERED USER

BACK TO SEARCH RESULTS

Mass Audubon
Policy & Advocacy Team
208 South Great Road, Lincoln, MA 01773
781.259.2172 hricci@massaudubon.org

August 30, 2022

Secretary Bethany Card
Executive Office of Environmental Affairs
Attention: MEPA Office
100 Cambridge Street Suite 900
Boston, MA 02114

Via Email: page.czepiga@mass.gov

Re: **Draft Special Review Procedure, Shellfish Aquaculture**

Dear Secretary Card

On behalf of Mass Audubon, I submit the following comments on the draft Special Review Procedure (SRP) for Shellfish Aquaculture proposed by the Division of Marine Fisheries (DMF). Mass Audubon supports the continued development of the aquaculture industry in Massachusetts, with appropriate geospatial planning and best management practices (BMPs). We recognize that some forms of aquaculture can have water quality benefits as well as economic value. We also support the use of shellfish restoration projects for Living Shorelines and other coastal resiliency projects, and recommend that regulatory streamlining be implemented to provide pathways for those projects to advance. This should include provisions allowing for no harvest sanctuaries for projects with goals primarily focused on habitat restoration, water quality, and climate resiliency. The current regulatory structure does not support those types of shellfish propagation projects.

As proposed, the SRP is likely to result in more than minimal individual and cumulative impacts. **A Programmatic review that first establishes appropriate locations and BMPs would be a more appropriate vehicle for planning and streamlining permitting for new aquaculture.** Mass Audubon has observed that intertidal and nearshore aquaculture projects are resulting in impacts including plastic debris, compaction, and displacement and disturbance of wildlife such as breeding and migrating coastal waterbirds. The potential impacts on other important habitat features such as eelgrass, including former eelgrass sites that may have the potential to re-grow if the site is not occupied by aquaculture, are unclear.

The 2021Massachusetts Ocean Management Plan[1] identifies the need for additional planning and BMPs for aquaculture:

> *Since the 2015 ocean plan, several shellfish-related initiatives were undertaken, including the Massachusetts Shellfish Initiative (MSI) and the Massachusetts Aquaculture Permitting Plan (MAPP). MSI involved EEA agencies, academics, shellfishermen, and environmental advocacy groups working together to create a strategic plan to maximize the economic, environmental, and social benefits of shellfish in Massachusetts. The MAPP project, assisted by ocean planning leadership and momentum, drew together multiple agencies to clarify the environmental permitting process for aquaculture in Massachusetts, resulting in a website outlining the permitting process and identifying important standards.* ***The next steps of the MAPP project include determining best***

[1] https://www.mass.gov/service-details/2021-massachusetts-ocean-management-plan, p.38

practices to minimize impacts and laying out a framework to assess cumulative impacts of aquaculture projects. *(p.38)* [emphasis added]

There are 94 aquaculture sites, occupying 226 acres, according to the 2021 Ocean Management Plan. No data has been presented on the impacts of aquaculture facilities to date. **There has been no systematic documentation or assessment of individual or cumulative impacts on marine debris, benthos, horseshoe crabs, birds, eelgrass, or other resources potentially impacted.** Since there is no program of baseline and follow up monitoring in place, there is no mechanism to objectively assess individual or cumulative impacts.

The MAPP is focused on guiding commercial aquaculture operators on how to obtain permits (www.massaquaculturepermitting.org/). The web tool and resources developed through MAPP provide overviews of the various permitting processes. These materials do not provide analysis or guidelines on how to avoid and minimize impacts to coastal or marine resources and wildlife, other than referring to other, pre-existing permitting processes. The BMP document on the state's website (www.mass.gov/service-details/aquaculture) is more than a decade old. It also is focused primarily on "how to" for aquacultural proponents, with only brief mentions of habitat and wildlife considerations, with references to the agency permitting processes.

Proposed SRP: The SRP would exempt new shellfish aquaculture projects from MEPA review if the project is under 2 acres in size, and provides for simplified notification procedures for projects between 2 and 10 acres in size, eliminating filing of an Environmental Notification Form and opportunity for public comments through MEPA. Eligible projects are those where the only state permit required is the DMF Section 57 Certification. However, a footnote in the proposed SRP provides that if it is determined after the Section 57 Certification is issued that other state permits are needed, the project can still escape MEPA review through a determination by the Agency and Secretary that no MEPA review is required. This could eliminate opportunities for public review through MEPA even if a permit is subsequently required such as a 401 Water Quality Certification, a permit under the Massachusetts Endangered Species Act, or a Superseding Order of Conditions from the Department of Environmental Protection (DEP) on a wetlands appeal.

Eligible projects are those under 322 CMR 15.04(1)(a)3. and 15.04(1)(b)1 that are "an open water system with minimal structures and no feeding" for "Shellfish." The definition of "Minimal Structures" in the DMF regulations are those that do not require an Individual Permit from the U.S. Army Corps of Engineers under the Massachusetts General Permit[2]. The Army Corp permit allows "the installation of buoys, floats, racks, trays, nets, lines, tubes, containers, and other structures" without the need for an Individual Permit. The proposed SRP refers to the use of "boxes, trays, pens, bags, or nets."

Impacts of Concern: While the DMF regulations define these projects as involving "minimal structures," the cumulative impacts of these structures and devices is likely in fact more than minimal. Impacts may include habitat displacement and unintentional release of plastic debris into the marine environment, which has been observed around some aquaculture sites. The proposed Aquaculture Description Form includes a section on bird deterrence plans for floating aquaculture. No information has been submitted on the impacts of these measures on birds or the environment (e.g. the use of zip ties is mentioned, and these may result in plastic debris). Impacts on eelgrass including interference with potential reestablishment of former eelgrass beds should be considered. In addition, it should be noted that some intertidal projects are being accessed by ATVs or pickup trucks, and the impacts of those activities (e.g. compaction, effects on benthos, disturbance of breeding or staging birds) have not been assessed in a systematic way.

[2] https://www.nae.usace.army.mil/Portals/74/docs/regulatory/StateGeneralPermits/MA/PN-GPFinal-RevApril2018.pdf?ver=2018-07-31-142949-100

<u>Proposed Cumulative Impact Summary is Inadequate:</u> The proposed SRP would require new projects to submit standard information on a DMF Aquaculture Description Form. We support the use of a standard form to gather and compile information on project locations, dimensions, gear types, and practices. **This will not, however, provide information sufficient for DMF to prepare a cumulative impacts summary, since there will be no monitoring of the impacts of these projects on resources.** Furthermore, the proposed process would be conducted solely by DMF and the project proponents, without opportunity for input from the public or local conservation commissions. It is unclear whether other agencies such as the Natural Heritage and Endangered Species Program (NHESP), DEP, or the U.S. Fish and Wildlife Service will be consulted in this cumulative assessment. The SRP is proposed as a one-year pilot, but with the possibility of extension for indefinite periods of time with approval of the Secretary. There is no provision for public dissemination of the cumulative summary after one year or future dates, nor any opportunity for public comment.

In conclusion, Mass Audubon recommends that DMF conduct a planning process and develop BMPs, consistent with the Massachusetts Ocean Management Plan. This should be conducted through an open and inclusive public planning process, which could utilize the Programmatic Review provisions in the MEPA regulations. The entities involved in this planning should be broadened from the existing MAPP participants, to include additional expertise on habitat and wildlife from federal and state agencies, nonprofit organizations, and academia. Following completion of a plan that identifies locations and BMPs to minimize conflicts with coastal and marine natural resources, MEPA review for projects consistent with that plan could be streamlined or in some instances potentially eliminated. However, this SRP is premature at this time given the lack of information on existing and potential future individual and cumulative impacts and BMPs to avoid, minimize and mitigate those impacts.

This regulatory review process should also address streamlining for shellfish restoration projects, including a permitting pathway for projects where the primary goals are for habitat restoration and climate resilience rather than commercial harvesting.

Mass Audubon would welcome the opportunity to engage with DMF and other organizations to provide further input.

Sincerely,

E. Heidi Ricci

E. Heidi Ricci
Director of Policy and Advocacy

Cc: Christian Petitpas, DMF
Lisa Rhodes, DEP
Jon Regosin, NHESP
Eve Schluter, NHESP
Dorothy McGlincy, Massachusetts Association of Conservation Commissions

Massachusetts Bays
NATIONAL ESTUARY PARTNERSHIP

Page Czepiga
Assistant Director
Massachusetts Environmental Policy Act

August 30, 2022

Submitted via MEPA public comment portal

RE: Special Review Procedure Request #16583, "Shellfish Aquaculture"

Dear Ms. Czepiga,

Thank you for the opportunity to comment on this request for a Special Review Procedure for siting of shellfish aquaculture. The Massachusetts Bays National Estuary Partnership has a long-term investment in the protection of coastal habitats in Ipswich Bay, Massachusetts Bay, and Cape Cod Bay, dating to the designation of the area as an Estuary of National Significance under Section 320 of the Clean Water Act. With this designation, we are mandated to develop a Comprehensive Conservation and Management Plan (CCMP), including targets for coastal habitat extent and condition. MassBays recently completed a process to determine achievable goals for eelgrass extent and improved health which are illustrated in our Ecohealth Tracking Tool (www.MassBaysEcohealth.org), and will be incorporated into a final CCMP later this year.

We are concerned that the SRP as proposed runs directly counter to the potential for expansion of eelgrass by natural or assisted restoration.

During the May 20th Shellfish Advisory Panel meeting (accessed via the recording provided in the filing), the current process for certification of aquaculture licenses was described as a burden for smaller farmers. Several references were made to the 26 pages plus attachments required for applicants. We agree that this can be a barrier, and suggest that rather than simply reducing the number of pages required to a bare minimum, the SRP should provide a more focused review process. In this way, reviewers will have documentation of potential beneficial and adverse impacts to nearshore habitat, especially eelgrass, a designated Special, Sensitive, or Unique (SSU) habitat under the Massachusetts Ocean Plan.

Eelgrass communities form landscapes of varying size and density from individual shoots, to discrete patches, to expansive meadows. These communities undergo continuous transformation due to a host of environmental conditions, and they can expand, contract, appear, and disappear along a temporal scale that ranges from annual to decadal.[1,2] Winter storms, acute water quality impairment events, natural temperature fluctuations and physical disturbances can significantly influence the extent and density of a meadow in any given year. To rebound after disturbance, the meadow can recolonize via seed dispersion (generally within 50 m of parent plants[3]) or by lateral clonal expansion which averages a 16 cm/yr expansion rate.[4] If a farm is installed in an area currently devoid but historically suitable for eelgrass, the eelgrass is unlikely to recolonize if aquaculture equipment is occupying the area, and if access/operations routinely disturb the sediment.

Shoot density, or the number of eelgrass plants in a given unit of area, is a confounding component of eelgrass mapping and resource management. Studies have documented that eelgrass patches of any density are associated with increased biodiversity and abundance.[5] Still, there is currently no regulatory definition of an eelgrass meadow in Massachusetts, much less one that describes the meadow based on density or patchiness metrics. This results in reduced resource protection when activities are proposed in

the low-density, difficult-to-detect portions of the meadow that are the most likely areas to be in a state of temporal flux.

Unfortunately, our ability to take these characteristics into account in Massachusetts waters is constrained by a lack of frequent eelgrass mapping or conditions assessments. For example, MassDEP maps eelgrass on a 5-year cycle, meaning that any one location is mapped only every five years. Beyond acreage, Massachusetts has no state-wide program for assessing eelgrass health, and yet this is an important indicator of overall habitat sustainability. Finally, Massachusetts does not have a standard protocol for determining eelgrass presence/absence at the site-specific level, especially with regard to density, thus leaving it up to applicants to determine whether a site impinges on established eelgrass habitat or not.

The proposed SRP does not take these habitat characteristics or mapping and assessment constraints into account. As a result we would anticipate multiple adverse impacts, including loss of existing, lower-density eelgrass beds; reduced potential for regrowth in historical eelgrass growing areas, and undocumented impacts.

We urge you to incorporate a more specific Aquaculture Description Form into the SRP application package. The form currently requests that proponents self-report eelgrass presence at their proposed site. As currently presented, the form could be an incentive for proponents to under-report or remove eelgrass to gain approval. To facilitate review of potential impacts, the form should be accompanied by a standard protocol to be used for assessing and documenting presence/absence of eelgrass in and adjacent to the proposed site. The protocol should include:

1. Recommended survey time-of-year to coincide with active eelgrass growth.
2. Preferred mapping method(s) and photo-documentation to assess eelgrass density. MassBays considers eelgrass of any density part of the meadow-community, a definition supported by the inter-agency Massachusetts Seagrass Working Group (MSWG). To address the need for a scientifically-based operational definition, the MSWG is currently drafting such a definition and plans to disseminate it along with management recommendations in a white paper.
3. Reference to eelgrass presence/absence in historic eelgrass maps. Assessment of the historical context of a site brings into consideration the complex above- and below-ground dynamics of an eelgrass meadow, and thus suitable areas can be better protected for future restoration, whether natural or intentional. We suggest that leases should not be certified in areas that showed eelgrass within the previous 10 years based on local and/or statewide mapping programs. This approach has precedence: Connecticut Department of Energy and Environmental Protections' Long Island Sound Blue Plan takes historic eelgrass sites into account for aquaculture siting decisions (https://portal.ct.gov/DEEP/Coastal-Resources/LIS-Blue-Plan/Long-Island-Sound-Blue-Plan-Home).

We also ask that you will consider the following recommendations prior to implementation of the SRP:

- The SRP should apply to all projects greater than 0.5 acres, rather than a 2-acre minimum. This standard aligns with the wetlands protection act requirements, and affords protection for eelgrass comparable to that for salt marsh. The higher minimum project size subject to review fosters a perception that eelgrass meadows are "less-than" habitat, when in fact eelgrass will likely become even more important to sustaining our coastal systems as climate change advances.
- The SRP should not be implemented until a process for tracking cumulative impact is in place, and a proposed limit to cumulative impact is drafted and shared for public comment. Simply documenting loss is not adequate for protection of the resource, nor is it sustainable resource management.

- During the Shellfish Advisory Panel meeting, reference was made to family members applying for adjacent aquaculture licenses. The SRP review should have a specific trigger for investigating potential segmentation of larger projects to avoid full MEPA review.

Finally, we understand that this approach is a one-year pilot. Any intention to implement the SRP beyond the pilot year should be subject to public comment. To facilitate assessment of its effectiveness, DMF should take up the following evaluation steps during the pilot year:

- Demonstrate and share results of DMF's protocol for documenting and assessing the cumulative impacts of aquaculture permits to eelgrass. The SRP should not be continued if we cannot track and respond to unacceptable impacts over time.
- Refine the standard protocol for site assessment (which we describe above, to be provided as an attachment to the Aquaculture Description Form) as needed.
- Prepare a summary report and map of leases granted under the SRP to accompany any proposal to continue implementation beyond the pilot year.
- Demonstrate outreach and enforcement efforts to prevent unauthorized expansion beyond certified aquaculture areas or placement in SSUs. This should include site visits – note that state regulators conduct their own site visits prior to licensing where eelgrass may be impacted in Florida (https://www.fdacs.gov/content/download/76600/file/FDACS-P-01758-Shellfish-Aquaculture-Leasing-Process-TB06.pdf), New Jersey (https://www.nj.gov/dep/fgw/pdf/marine/shellfish_leasing_policy_atlantic.pdf), and Rhode Island (personal communication, Coastal Resources Management Council).
- Partner with researchers to monitor changing conditions in adjacent eelgrass (positive or negative) for a subset of leases, to evaluate the effectiveness of the 25' buffer and document potential benefits to eelgrass of aquaculture installations.

Thank you again for the opportunity to comment. We look forward to working with you to advance aquaculture siting that is sustainable not only for shellfish production, but for the larger estuarine system.

Sincerely,

Pam DiBona
Executive Director

Citations

[1]Frederiksen, Morten & Krause-Jensen, Dorte & Holmer, Marianne & Laursen, Jens Sund. (2004). Spatial and temporal variation in eelgrass (Zostera marina) landscapes: Influence of physical setting. Aquatic Botany. 78. 147-165. 10.1016/j.aquabot.2003.10.003.

[2]Morten Frederiksen, Dorte Krause-Jensen, Marianne Holmer, Jens Sund Laursen. (2004) Long-term changes in area distribution of eelgrass (Zostera marina) in Danish coastal waters. Aquatic Botany. 78(2) 167-181. 10.1016/j.aquabot.2003.10.002.

[3]Ruckelshaus, M.H. (1996). Estimation of genetic neighborhood parameters from pollen and seed dispersal in the marine angiosperm Zostera marina. Evolution 50(2):865-864. 10.1111/j.1558-5646.1996.tb03894.x

[4]Olesen, Birgit & Sand-Jensen, K. (1994). Patch dynamics of Eelgrass Zostera marina. Marine Ecology-progress Series - MAR ECOL-PROGR SER. 106. 147-156. 10.3354/meps106147.

[5]Washington State Department of Natural Resources. (2013). Operational Definition of an Eelgrass (Zostera marina) Bed. Appendix J Technical Memorandum.

The Nature Conservancy
Protecting nature. Preserving life.™

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Bethany A. Card, Secretary
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

RE: Aquaculture Special Review Procedure

August 30, 2022

Dear Secretary Card,

Thank you for your leadership on coastal restoration and aquaculture.

I am writing to respectfully submit this letter in general support of the Division of Marine Fisheries' (DMF) request that the Executive Office of Energy and Environmental Affairs (EEA) authorize the establishment of a one-year pilot Special Review Procedure (SRP) for certain aquaculture projects. We believe that this pilot program will ensure environmental safeguards related to aquaculture development while fostering permitting efficiencies for a critical sector contributing to ecosystem recovery and the blue economy.

The Nature Conservancy (TNC) is an international conservation organization working to deliver lasting solutions to complex environmental challenges that result in a world where people and nature thrive. We know that coastal resources around the globe and here in Massachusetts are heavily utilized and impacted by land use practices and nearshore development. TNC continues to work toward scaling interventions that address coastal environmental degradation. Our work has focused on advancing nature-based solutions including shellfish restoration and more recently harnessing the power of the aquaculture industry to deliver positive environmental outcomes, namely water quality and functional habitat improvements (www.nature.org/massaquaculture).

TNC respectfully requests that the pilot SRP, if implemented, undergo a formal review that engages stakeholders to help inform any future action and adaptive management. Additionally, we request that the SRP be utilized as an opportunity for learning and developing best management practices, particularly related to cumulative impacts of aquaculture-environmental interactions. We request EEA provide additional resources, such as full-time staff, to DMF or other EEA agencies or partners that are necessary to ensuring cumulative impacts research, program review, a transparent process, and stakeholder input.

The scale of the environmental challenges facing our coastal communities and environment is only growing and efficient permitting for projects that result in positive environmental outcomes is critically important. Should the aquaculture pilot SRP prove beneficial, we request that information gleaned from the process be incorporated into ongoing efforts to improve permitting processes and efficiencies for ecological restoration projects.

In a best-case scenario, the pilot SRP would introduce efficiencies in permit review for environmental impacts from aquaculture industry development -- a benefit to project proponents and permit reviewers, alike. Please accept this letter of general support for establishing an

aquaculture pilot SRP, with suggestions for its implementation and consideration of other project types, to improve environmental permitting efficiencies. Thank you for your time and consideration. Please feel free to ask any questions. I can be reached at stephen.kirk@tnc.org.

Respectfully,

Stephen Kirk

Director, MA Coastal Program

The Nature Conservancy

Stephen.kirk@tnc.org 508-274-0775

Aquaculture SRP

Nancy Civetta <Nancy.Civetta@wellfleet-ma.gov>

Tue 8/30/2022 4:11 PM

To: MEPA (EEA) <mepa@mass.gov>

Dear Ms. Card:

The Special Review Procedure (SRP) seems like a good way to collect needed information about new proposed aquaculture sites and provides a seemingly more efficient and easier way to proceed for most folks looking to get into the aquaculture business. We agree that the process needed simplification and believe that the proposed SRP achieves that goal. We hope that the cumulative impacts section that DMF will provide by working with the municipality and project proponents will not present any obstacles to what should turn out to be a less complicated and more prompt process. We thank you for your efforts in making this process a way to honor the needed public participation with transparency and accountability yet through a more timely and accessible procedure for the applicants. We appreciate your support of the aquaculture industry, which in Wellfleet in 2019 was worth close to $8M to the town's shellfishing community. Shellfishing is the largest year-round contributor to our local economy and providing more manageable avenues to spur the next generation to become involved in it is a win for everyone, including the state.

Sincerely,
Nancy Civetta

Nancy Civetta
Shellfish Constable
Town of Wellfleet
C: 617-901-7193
O: 508-349-0325
E: nancy.civetta@wellfleet-ma.gov
300 Main St.
Wellfleet, MA 02667
Check for news and updates on Facebook.

AQUACULTURE DESCRIPTION FORM

Clear Fields

Name: Last_____ **First**_____ **M.I.**_____

Business Name (optional):_____

Mailing Address_____

City/Town_____ **State**_____ **ZipCode**_____

Telephone_____ **Cell Phone**_____

E-Mail Address_____

A. SITE DESCRIPTION

Location of proposed aquaculture license site(s) and access routes (Include a site map in USGS 1:24,000 or 1:25,000 format with site boundaries clearly outlined and both current and historic Massachusetts Department of Environmental Protection (MassDEP) mapped eelgrass layers depicted on the map. The MA-ShellfAST tool may be used for generating the map and measuring distances/acreage).

City/Town:_____

Shellfish Growing Area (SGA): _____

# of Acres:_____

Site boundaries defined by latitude and longitude in decimal degrees (i.e. 42.36115º, -71.057083º):

_____

Have you conducted a survey of the site (Y/N)? _____ Date? _____

Method of Survey:

_____

Average Depth at Mean Low Tide (MLW): _____

Mean High Tide (MHW): _____

The site is located in an: ☐ intertidal area; ☐ subtidal area; ☐ spans both intertidal and subtidal areas.

What type of sediment or bottom substrate is on the site? (Benthic Habitat Conditions):

_____

Is eelgrass currently present on or within twenty-five (25) ft. of the proposed site[1] (Y/N)?

If eelgrass is present or currently/historically mapped by DEP within the shellfish growing area, what is the shortest distance to actual or mapped eelgrass from the proposed site? _____ft.

Are there shellfish currently on the site (Y/N)?

If yes what species and approximate densities?

_____

Is the proposed grant site located within an Area of Critical Environmental Concern (**ACEC**) (Y/N)?

_____

Is the proposed grant site located within Natural Heritage Endangered Species Project (**NHESP**) mapped habitat (Y/N)? ***If yes, you must submit a MESA Project Review Checklist to NHESP.***

_____

Is the proposed grant site located within an Outstanding Resource Waters (Y/N)?

Is there an Environmental Justice (EJ) population located within 1-mile of the project site (Y/N)?

If so, please complete the attached supplement to this form for projects located within 1-mile of EJ populations.

Describe whether alternative locations were considered and identify the siting criteria used to select this site and the characteristics of the site that make it suitable for aquaculture use. It may be helpful for this evaluation to be based on the siting criteria identified in DMF's Shellfish Planting Guidelines and the Army Corps of Engineers General Permit for Aquaculture.

Has the site been used for private shellfish propagation within the last two years (Y/N)?

Has the site been used for municipal shellfish propagation within the last two years (Y/N)?

1. Proposed aquaculture license sites with eelgrass present within the footprint or within 25 ft. of eelgrass will not be granted certification by DMF.

B. SPECIES TO BE CULTURED

What species of shellfish do you plan to cultivate? (Select all that apply)

- ☐ Eastern Oyster
- ☐ Quahog or Hard Clam
- ☐ Softshell Clam or Steamer
- ☐ Surf Clam
- ☐ Razor Clam
- ☐ Bay Scallop
- ☐ Blue Mussel
- ☐ Other _____

Do you propose on-bottom placement of cultch or spat on shell on the site (Y/N)?

If yes, explain.

C. GEAR

What methods of culture will be used (specify by species if necessary)?

On- bottom ☐ Off- bottom submerged ☐ Off- bottom floating ☐

Describe the type of gear to be utilized for each species to be cultured, include dimensions (Cages, Racks, Trays, Bags, Nets, Floating): ***Depending on the gear type used, the project may require additional permitting by the Massachusetts Department of Environmental Protection (MassDEP). Consult with your Harbormaster, and if needed, with the MassDEP Waterways Program.***

---

*Include with your submission of this form a site map on a USGS 1:24,000 map with site boundaries clearly outlined and a cross-section schematic of the gear to be deployed on the site.

If you will utilize floating gear, what measures will you take to deter birds (bird deterrence plan required)?

- ☐ Spikes
- ☐ Zip ties
- ☐ Kites/streamers
- ☐ Faux predators
- ☐ Wire cage exclusion
- ☐ Sweeps/spinners
- ☐ Sonic deterrents
- ☐ Other

Please describe your bird deterrence plan:

_____

What methods will you utilize to harvest shellfish? (Hand, Drag, Other) Please describe:

_____

How will the proposed license site be marked? (Buoy color, Type, Lines, Anchor)

_____

How will you access the license site?

What equipment do you plan on utilizing to maintain the license site and transport product?

Vehicle: Make: _____ Model: _____

Boat: Make: _____ Model: _____

Will any accessory structures be used on the license site? (barge, float, upweller, etc.)

Will this be a seasonal operation (gear and product removed from site in winter) or year-round?

Please include any additional information here:

D. CUMULATIVE IMPACTS

After voting to grant the site license at a duly advertised public hearing (M.G.L. c.130 §60), the Select Board of the municipality must submit a request for site certification to the Division of Marine Fisheries (DMF). A site inspection that may include a site survey will be performed by DMF. If DMF determines that issuance of the site license and operational activities thereunder will have no substantial adverse impacts to natural resources and existing fisheries, DMF will issue a conditional certification letter to the municipality and include a summary table that identifies other existing and conditionally certified aquaculture sites, gear types, and acreage within the same embayment as the proposed site.

This table will be used to assess cumulative impacts if the project is subject to environmental review by the Massachusetts Environmental Policy Act (MEPA) Office and should be submitted as an attachment with your MEPA filing. If the project is subject to the MEPA Special Review Procedure (SRP), the applicant hereby acknowledges and agrees to following the procedures set forth in the SRP. The SRP can be viewed here.

All information furnished on this application is true and accurate to the best of my knowledge. I will notify the Division Marine Fisheries Shellfish Sanitation and Management Program immediately of any changes.

Signature of Applicant_____ Date_____

Division of Marine Fisheries

ATTN: Aquaculture Coordinator

706 South Rodney French Boulevard

New Bedford, MA 02744

Phone: (508) 742-9766

SUPPLEMENT TO DMF AQUACULTURE DESCRIPTION FORM

Only For Projects Located Within 1 Mile of Environmental Justice (EJ) Populations

Describe any public hearings or other public outreach conducted in relation to the project. Were there any concerns raised during the municipality's public hearing or other process? If so, how were they resolved?	
Indicate whether the project is located within a municipality that exhibits "vulnerable health EJ criteria," as indicated on the DPH EJ Tool, and specify the relevant public health criteria. *Navigate to the DPH EJ Tool, click the "EJ Data and Reports" tab at the top of the webpage, find your municipality in the table, review the "Vulnerable Health EJ Criteria Met" column of the table.*	*E.g., Town of XX meets vulnerable health EJ criteria for heart attack, low birth weight, childhood lead, childhood asthma.*
Identify potential environmental or public health benefits of the project that may extend to the identified EJ populations.	☐Water quality benefits ☐Recreational opportunity ☐Commercial opportunity ☐Other (please specify)
Identify any environmental or public health impacts of the project that may extend to the identified EJ populations.	☐Bird attraction/water quality degradation ☐Hindrance of recreational opportunity ☐Hindrance of subsistence activities ☐Other (please specify)

FY2022
PROGRAM ELEMENT EVALUATION REPORT

OF THE

GROWING AREA CLASSIFICATION ELEMENT

DIVISION OF MARINE FISHERIES
AND
DEPARTMENT OF PUBLIC HEALTH
COMMONWEALTH OF MASSACHUSETTS

PREPARED BY

AMY FITZPATRICK
SHELLFISH SPECIALIST
FDA OFFICE OF STATE COOPERATIVE PROGRAMS
AND
J. QUENTIN FORREST
GROWING AREA SUBJECT MATTER EXPERT
FDA CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

ON

<ENTER DATE - MONTH/DAY/YEAR – FORMAT OF FINAL ISSUED TO STATE >

PROGRAM ELEMENT EVALUATION REPORT

STATE: Massachusetts (MA)

PROGRAM ELEMENT EVALUATED: Growing Area Classification

FREQUENCY OF EVALUATION (See Table 1): Annual

DATES OF EVALUATION: August 7 – August 16, 2022

PERIOD UNDER REVIEW: The evaluation consisted of a review of growing area reports and supporting documents for the growing areas selected dated 2019-2021.

A. Status of Previous Program Evaluation (s)

1. Summary of deficiencies from 2016-2018 and 2021 PEERs

The Massachusetts (MA) Division of Marine Fisheries (DMF) remains under an action plan for deficiencies documented during the 2016-2018 growing area classification evaluations and the FY2021 evaluation. The deficiencies cited were due to the program not meeting National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) requirements.

The FDA, to date, has not received an action plan from the MA DMF for the four (4) deficiencies documented in the 2016 growing area classification (GA) program element evaluation report (PEER). On November 19 and November 27, 2018, the MA DMF provided two (2) action plans to address the deficiencies documented in the 2017 GA PEER. The MA DMF provided an action plan to address the deficiencies identified in the 2018 MA GA PEER on August 16, 2019. The FDA received an action plan from the MA DMF for the one (1) deficiency documented in the FY2021 GA PEER on December 3, 2021. The following is a brief description of the deficiencies remaining under the action plans with the years and NSSP MO citation:

(2016-2018) Chapter IV@.03 C. (2) (c) (iii): The re-opening criteria for conditional area management plans (CAMPs) must meet the minimum criteria of the NSSP and must have studies establishing sufficient elapsed time for the reduction of coliform levels in the shellstock to pre-closure levels; the area must be in the closed status until the event is over and 21 days have passed (WWTPs). No cleansing studies or data have been presented to date to support the MA DMF's current automatic growing area re-openings after closures due to rainfall in conditionally managed growing areas.
(2017-2018) Chapter IV@.01 D. (1) (a): Pollution sources identified in growing areas were not identified and evaluated.
(2017-2018) Chapter IV@.01 C. (3) (a) (iii): Pollution sources identified in the sanitary survey are not being reevaluated in triennial reports.
(2017-2018) Chapter IV@.03 E. (5) (b): Dilution analyses for established prohibited areas around WWTP outfalls were not provided and were not part of the sanitary surveys or triennials.
(2016-2018) Chapter IV@.05 and Chapter IV @.01 D. (1) (a): Marinas and mooring areas are not properly classified and/or identified and evaluated as potential pollution sources which may affect the growing area.
(2017-2018) Chapter IV@.03 A. (5) and Chapter IV@.01 C. (3) (a) (v): Growing areas

with failing water quality monitoring stations are placed in the "closed" status by the MA DMF instead of re-classifying the growing areas.
(2018) Chapter IV @.02 B.: Water sampling stations were not always present in locations that were adequate to effectively evaluate all pollution sources.
(2017-2018) Chapter IV. @.03 C. (2): There were no written conditional area management plans (CAMPs) for conditional areas.
(2021) Chapter I @.01 D.: Requires a memorandum of agreement shall be developed between agencies when more than one (1) is involved in the administration of the statewide shellfish safety and sanitation program to define each agency's responsibilities.

2. State Actions to Correct Deficiencies from 2016-2018 and 2021 PEER

The MA DMF took the following actions to address the deficiencies identified in the 2016-2018 and FY2021 evaluations:

(2016-2018) Chapter IV@.03 C. (2) (c) (iii): The MA DMF submitted proposal 19-117 to the 2019 Interstate Shellfish Sanitation Conference (ISSC) requesting consideration of a change to eliminate the requirement for cleansing studies in conditionally approved areas. The proposal was adopted into the 2019 National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance.
(2016-2018) (tied together with deficiencies #3 and #7) Chapter IV@.01 D. (1) (a): The MA DMF assessed and reclassified marinas and mooring areas in 2021 and 2022. On October 6, 2021, the MA DMF provided a list of new (2021) delineated mooring areas (attachment 1). The DMF continues to make progress on identifying, assessing, and reclassifying mooring areas.
(2017-2018) (tied together with deficiencies #2 and #7) Chapter IV@.01 C. (3) (a) (iii): The DMF continues to make progress on assessing pollution sources identified in the sanitary survey(s) as triennial reevaluations are completed.
(2017-2018) Chapter IV@.03 E. (5) (b): On August 15, 2022, the MA DMF provided dilution analyses for the WWTPs in BB10, BB31, and BB36 to address this deficiency; refer to section B. 3. for details.
(2016-2018) (tied together with deficiencies #2 and #3) Chapter IV@.05 and Chapter IV @.01 D. (1) (a): The MA DMF reclassified two (2) marina areas on April 30, 2021. The DMF reclassified seven (7) mooring areas on July 1, 2022.
(2017-2018) Chapter IV@.03 A. (5) and Chapter IV@.01 C. (3) (a) (v): Growing areas with failing water quality monitoring stations are placed in the "closed" status by the MA DMF instead of re-classifying the growing areas. The MA DMF submitted proposal 19-116 to the 2019 ISSC requesting consideration of a change to allow for the use of the closed status for a period 'not to exceed more than one year prior to a reclassification'. The proposal was assigned to committee for deliberation at the ISSC.
(2018) Chapter IV @.02 B.: The MA DMF conducted an evaluation of sample station locations in all growing areas in <<year>>.
(2017-2018) Chapter IV. @.03 C. (2): On February 27, 2020, the MA DMF provided seasonal CAMPs, annual reports, and legal notices for opening and closure for growing areas MB6.1, CCB27, and CCB29.
(2021): On January 26, 2021, the MA DMF reported that they had met with the MA Environmental Police Office of Law Enforcement (OLE) and with the MA Department of Public Health (DPH) Food Protection Program (FPP) on the three (3) agency MOA. The MA DPH provided a draft to the FDA on July 18, 2022.

3. Status of Action Plans from 2016-2018 and 2021 PEERs

The status of the 2016-2018 and FY2021 action plans are as follows:

(2016-2018) Chapter IV@.03 C. (2) (c) (iii): unresolved - The MA DMF is working with the ISSC committee on guidance for states to implement the new requirement(s) adopted at the 2019 ISSC. The FDA and the MA DMF, in a tracking document entitled MA Deficiencies_04.20.2021, stated the MA DMF needs to provide the data and analysis (water and tissue) supporting reopening criteria for areas impacted by WWTP such as cleansing studies.
(2017-2018) Chapter IV@.01 D. (1) (a): **resolved**
(2017-2018) Chapter IV@.01 C. (3) (a) (iii): partially resolved - During the current evaluation, the New Bedford WWTP was not reevaluated in growing area BB11. The >20 boats moored in Aucoot Cove (BB31), Blankinship Cove and Planting Island Cove (BB32), and the mooring areas assessed in 2013 in BB36 were not reevaluated in 2019. Refer to section B. 2. h. for details.
(2018) Chapter IV @.01 C. (5) (a) (i)-(iii): resolved
(2017-2018) Chapter IV @.01 D. (1) (d): resolved
(2017-2018) Chapter IV@.03 E. (5) (b): unresolved - During the current evaluation, the WWTPs in BB10 (Smith Neck South Coastal), BB11 (Dartmouth), BB13 (New Bedford and Dartmouth), BB31 (Aucoot Cove), and BB36 (Wareham) did not have documentation to show how the size of the prohibited classification was determined at the prohibited/approved classification line. Refer to section B. 2. k. for details. On August 15, 2022, the MA DMF provided dilution analyses for the WWTPs in BB10, BB31, and BB36 to address this deficiency; refer to section B. 3. for details.
(2016-2018) Chapter IV@.05 and Chapter IV @.01 D. (1) (a): partially resolved
(2017-2018) Chapter IV@.03 A. (5) and Chapter IV@.01 C. (3) (a) (v): unresolved - The MA DMF ISSC proposal 19-116 was sent to committee for deliberation by the general assembly at the 2019 ISSC. In the meantime, the MA DMF continues to implement its policy of closing the area around sample stations with water quality that fails to meet classification standards for a one (1) year period prior to re-classifying the growing area or portion thereof.
(2018) Chapter IV @.02 B.: resolved
(2017-2018) Chapter IV@.03 C. (3) (a): resolved
(2017-2018) Chapter IV. @.03 C. (2): unresolved - The current evaluation found growing areas BB11.3, BB12.5, BB25.2, SC48.4, SC48.5, SC48.7, SC48.8, SC49.1, SC49.2, SC49.3, SC49.4, SC50.1, SC51.1, and SC51.2 do not have conditional area management plans. Refer to section B. 2. k. for details.
(2021) Chapter I @.01 D.: unresolved – The MO requires a memorandum of agreement shall be developed between agencies when more than one (1) is involved in the administration of the statewide shellfish safety and sanitation program to define each agency's responsibilities. The administration of the MA shellfish sanitation program related to growing area classification is a shared responsibility between two (2) agencies. Two (2) divisions within the MA Executive Office of Energy and Environmental Affairs, MA DMF and Office of Law Enforcement, (the MA Environmental Police (MA OLE)), and the MA Department of Public Health, Food Protection Program (MA DPH). The MA DMF continues under a 2021 action plan for this deficiency.

4. FDA Follow-up Regarding Previous PEERs Deficiencies and Action Plans

On January 27, 2022, the FDA provided interagency MOAs from Connecticut and New Hampshire (with permission) as examples at the request of the MA DMF.

B. Status of Current Evaluation

1. Total Number of Growing Areas Evaluated

The growing area classification element will be evaluated by the FDA shellfish specialist at a frequency determined by a risk assessment and whether the state is on an action plan. Pursuant to the FDA Molluscan Shellfish Compliance Program (CP7318.004) the overall risk of high or low is based on a score as determined by three (3) risk factors; production, classification complexity, and illness outbreaks. Table 1 contains the point value for each risk factor with the growing area classification element for MA, the total score, and the overall risk determination. Based on the overall risk of high, the element will be evaluated annually.

Table 1: MA Growing Area Risk Assessment Form FY2022

Risk Factors	Score (0-4)	Rating (H, MH, M, ML, L)	Explain Rating
PRODUCTION	4	H	The three (3) year average for total shellfish harvested from 2018 - 2020 >340M pounds.
CLASSIFICATION COMPLEXITY	4	H	115 of 305 growing areas (37%) have conditional areas
ILLNESS OUTBREAKS	1	L	No outbreaks in the past five (5) years.
	Total: 9	Overall Risk (H or L): **H**	

MA monitored 305 shellfish growing areas in FY2022; the current evaluation covered 14 growing areas. The shellfish specialist used Table 2, Number of Units to Select for Evaluation, in the FDA Molluscan Shellfish Compliance Program 7318.004 and the overall risk, to determine the number of areas selected for evaluation.

Table 2: MA Growing Areas Evaluated FY2022

Growing Area Name	Classification(s)
BB10 Smith Neck South Coastal	approved, prohibited
BB11 Dartmouth East Coastal	approved, conditionally approved, prohibited
BB12 Apponagansett Bay	approved, conditionally approved, prohibited

Growing Area Name	Classification(s)
BB13 Clark Cove	conditionally approved, prohibited
BB21 Nasketucket Bay	approved, prohibited
BB22 Little Bay	conditionally approved, prohibited
BB25 Mattapoisett Harbor	approved, conditionally approved, prohibited
BB31 Aucoot Cove	approved, prohibited
BB32 Sippican Harbor	approved, conditionally approved, prohibited
BB36 Wareham River	approved, conditionally approved, prohibited
SC48 Stage Harbor	approved, conditionally approved
SC49 Oyster Pond River	approved, conditionally approved
SC50 Oyster Pond	approved, conditionally approved, prohibited
SC51 Mitchell River and Mill Ponds	approved

2. Current Findings

a. Administration [Chapter I. @.01 A.]

The MA DMF meets the requirements of Chapter I. @.01 A. (1) (a). The DMF is responsible for the classification of shellfish growing areas.

b. State Laws and Regulations [Chapter I. @.01. B.]

The MA DMF meets the requirements of Chapter I. @.01 B. The MA DMF has not adopted the NSSP MO into law. The MA DMF maintains their own laws and regulations to provide an adequate legal basis for the growing area classification program element outlined in Chapter I. @.01 A. (1) (a). The state laws and regulations that provide the legal basis or authority to classify, open and close, and manage growing areas are as follows and can be accessed online at: https://malegislature.gov/laws/generallaws and https://www.mass.gov/doc/322-cmr-16-shellfish-sanitation-harvest-handling-and-management/download

i. Laws:

"Massachusetts General Law (M.G.L.) chapter (ch.) 130 § 74 Determination of contaminated areas; notice of results; The division of marine fisheries shall examine from time to time as conditions may require, or upon request of the commissioner of public health, the mayor or city manager of a city, or the selectmen or town manager of a town, the coastal waters and flats of the commonwealth and samples of shellfish therein or thereon in order to determine what areas thereof are so contaminated that shellfish obtained therefrom are unfit for food and dangerous to the public health. The division of

marine fisheries shall forward the results of all tests as directed by the commissioner of public health. If, after such examination, either the department of public health or the division of marine fisheries determines that such contamination exists, it shall, by written order, promulgate definite bounds of the area or areas so determined to be contaminated, and may specify the period of time during which such determination shall be in effect. Before such determination shall be in effect, such department or division making the determination shall:

(1) Publish the results of its determination thereof in a newspaper published in each city and town in which or adjacent to which any contaminated area is situated.
(2) File in the office of the clerk of every such city or town the results of the determination.
(3) Cause to be posted at points on or near every such area a description thereof, specifying said bounds and a statement that such an area is contaminated.
(4) If the department of public health makes the determination, notify the directors of the division of marine fisheries and the division of law enforcement of its determination by filing with them properly authenticated copies, certified by the secretary of state, of its determination, publication, filing and posting.
(5) If the division of marine fisheries makes the determination, notify the director of the division of law enforcement of its determination by filing with him properly authenticated copies, certified by the secretary of state, of its determination, publication, filing and posting.

Whenever, as a result of a subsequent examination of an area or areas determined by the division of marine fisheries or the department of public health to be contaminated, such division or said department, as the case may be, determines that the shellfish in such area or areas are safe to use as food, notice of such determination shall be published immediately, and provided to the directors of the division of marine fisheries and the division of law enforcement, in the case of a determination by the department of public health, and to the director of the division of law enforcement in the case of a determination by the division of marine fisheries; provided, however, that if the department of public health or the division of marine fisheries has specified a period of time during which the determination of pollution shall be in effect, such publication and notice shall not be required if such period has expired. The record of any examination hereunder and the bacteriological counts made therein shall be subject to inspection upon request.

Personnel at the department of public health and the division of marine fisheries in the performance of their duties under this section, may enter upon and pass through or over private lands or property whether or not covered by water.

The presentation in evidence by any officer of the commonwealth empowered to enforce this chapter of a document attested to by the commissioner of the department of public health or the director of the division of marine fisheries or either of their designees to the effect that the provisions of this section have been complied with shall be prima facie evidence that an effective determination has been made.

The department of public health and the division of marine fisheries, acting jointly, after consultation with the department of environmental protection, can promulgate rules and regulations establishing standards and criteria for the classification of all shellfish

growing areas within the commonwealth. Such standards and criteria shall conform at a minimum to those established by the national shellfish sanitation program.

This section shall not apply to scallops or conch unless scallops or conch are specifically included in such determination."

"M.G.L. ch.130 §74A Emergency designation of contaminated shellfish areas; enforcement; notice to local authorities: Both the department of public health and the division of marine fisheries shall have the authority immediately to designate shellfish areas as contaminated and that shellfish obtained therefrom are unfit for food and dangerous to the public health, in the event of an emergency as determined by either the department of public health or the division of marine fisheries. Such designation shall be reported to the division of law enforcement, and, in the case of a determination by the department of public health, to the division of marine fisheries, who shall take the necessary action to prevent the taking of shellfish from such area for human consumption and so notify local authorities in each instance. Such determination shall be in effect until subsequent examination, initiated not more than thirty days after the emergency has been determined, shows the shellfish from such area to be safe for human consumption and the said department or division which designated the emergency declares it to be over. In the event that the department of public health determines that there is an emergency, the commissioner of public health shall have the power to direct the activities of all employees of the division of marine fisheries who are regularly engaged in monitoring the condition of shellfish during that emergency.

This section shall not apply to scallops or conch unless scallops or conch are specifically included in such determination."

ii. Regulation(s):

"322 Code of Massachusetts Regulation (CMR) 16.00: SHELLFISH SANITATION, HARVEST, HANDLING AND MANAGEMENT [sic]

16.01: Background and Purpose
The National Shellfish Sanitation Program (NSSP) is a program under the U.S. Food and Drug Administration (FDA) to promote the sanitary control of molluscan shellfish produced, harvested and sold for human consumption. The Interstate Shellfish Sanitation Conference (ISSC) comprised of representatives of the federal government, the states and industry, reviews, revises and updates the NSSP as needed. The NSSP has established a Model Ordinance (MO), which is updated on a biannual basis. The MO sets forth stringent guidelines addressing the harvest, handling, transportation and sale of shellfish to ensure that risks to public health associated with the consumption of shellfish are avoided.

To safeguard public health and to allow for shellfish produced, harvested and sold for consumption to enter interstate commerce, states must manage commercial shellfisheries in a manner that conforms to the NSSP's MO. The actions required by the MO include, but are not limited to: establishing shellfish growing area classifications and subsequent restrictions on the harvest of contaminated shellfish; adopting best practices for the harvest, handling and transport of shellfish to minimize the risk of foodborne illness; establishing a framework that provides for the expeditious recall of nonconforming shellfish product; addressing risks associated with *Vibrio*

parahaemolyticus; describing the conditions by which contaminated shellfish harvest may be conducted; and managing marine biotoxin events.

The Division of Marine Fisheries manages its shellfish resources and commercial shellfish fisheries in strict conformity with the NSSP's MO. The Division has adopted the provisions of the MO in regulations at 322 CMR 16.00 to provide notice to the public of the comprehensive requirements applicable to the safe management of commercial shellfisheries and give the Division, through the Massachusetts Environmental Police, the authority to enforce against violations of 322 CMR 16.00. 322 CMR 16.00 also serves to safeguard public health, maintains consumer confidence and promotes the state's shellfish fisheries."

16.02: General Definitions

16.03: Shellfish Growing Area Classification
"(1) Background and Purpose. The NSSP's Model Ordinance requires that states regulate the waters under their jurisdiction that support or could support shellfish and determine if these areas meet the sanitary conditions necessary to allow the harvest of shellfish for human consumption.

The Division has met this requirement by its sanitary classification of the approximately 1.7 million acres of the overlying waters under the jurisdiction of the Commonwealth. The Division has further classified these waters into 303 designated shellfish growing areas based on hydrographical and geographic features.

The Division's shellfish growing area classifications are based on an extensive assessment of local environmental conditions and pollution sources, including impacts to water quality in the area. The principal components of these sanitary surveys, which are conducted by Division staff trained by the U.S. Food and Drug Administration, include:
(a) an evaluation of pollution sources that may affect an area;
(b) an evaluation of the hydrographic and meteorological characterizes that may affect the distribution of pollutants; and
(c) an assessment of water quality.

Additionally, shellfish are tested for various poisonous or deleterious substances based on assessment of pollution sources identified by the sanitary survey and as a result of oil and chemical spills. The result of the sanitary survey is summarized in a written report by the Division.

In accordance with M.G.L. c. 130, §§ 74 and 74A, the Division classifies a shellfish growing area based on the results of the sanitary survey and as required by the Model Ordinance. Depending on the extent to which an area is contaminated, the Division will make one of the following classification determinations for the area: Approved; Conditionally Approved; Restricted; Conditionally Restricted; and Prohibited. The Division's classification of the shellfish growing area determines whether the harvest of shellfish is approved with or without restriction or prohibited in all circumstances.

The Division manages the statewide shellfish safety and sanitation program to ensure shellfish are safe to harvest and protect public health. The municipalities control the regulation and management of both commercial and non-commercial shellfisheries in waters under municipal control, provided such waters are classified by the Division as

Approved or Conditionally Approved while in an “Open Status”. Certain Conditionally Approved areas that are predictably impacted by rain events can be managed by municipalities under an NSSP required Conditional Area Management Plan.

Municipalities are then allowed to open and close these Conditionally Approved areas based on performance standards and subject to annual evaluation by the Division. Areas classified as Restricted or Conditionally Restricted are subject to state control, unless the Division has approved a local Shellfish Conservation and Management Plan pursuant to M.G.L. c. 130, § 75. In such cases, municipalities are granted limited shellfisheries management authority when these areas are in an Open Status, but are not allowed to change the sanitary status of these areas from open or closed on their own.

The scope of 322 CMR 16.03 includes a description of each of the shellfish growing area classifications and sets forth the requirements applicable to each classification and the process for providing public notification regarding the classification and status.

(2) Shellfish Growing Area Classifications and the Harvest of Shellfish under Certain Certifications.

(a) Approved. An Approved shellfish growing area has been subject to a sanitary survey that demonstrates shellfish within the growing area meet the sanitary conditions necessary for direct human consumption. An Approved shellfish growing area may be open to the harvest of shellfish for direct human consumption, subject to municipal shellfish management regulations established in accordance with M.G.L. c. 130, § 52. The harvest of shellfish from Approved shellfish growing areas may be prohibited by the Division under an emergency designation of contamination made in accordance with M.G.L. c. 130, § 74A.

(b) Conditionally Approved. A Conditionally Approved shellfish growing area has been subject to a sanitary survey that demonstrates shellfish within the growing area meet the sanitary conditions necessary for direct human consumption under certain conditions described in a Conditional Area Management Plan. The status of a Conditionally Approved shellfish growing area may change from Open to Closed in response to environmental conditions such as impacts to water quality from pollution sources or other predictable changes in water quality. The harvest of shellfish from a Conditionally Approved shellfish growing area in the Open Status may be allowed for direct human consumption, subject to municipal shellfish management regulation established in accordance with M.G.L. c. 130, § 52. The harvest of shellfish from a Conditionally Approved shellfish growing area may be prohibited by the Division under an emergency designation of contamination made in accordance with M.G.L. c. 130, § 74A or under the provisions of a Division-approved Conditional Area Management Plan for that area.

(c) Restricted. A Restricted shellfish growing area has been subject to a sanitary survey that demonstrates shellfish within the growing area contain a limited degree of contamination at all times. The harvest of shellfish from a Restricted shellfish growing area for direct human consumption is prohibited, except as provided at 322 CMR 16.03 (2)(f).

(d) Conditionally Restricted. A Conditionally Restricted shellfish growing area has been subject to a sanitary survey that demonstrates shellfish within the growing area contain a limited degree of contamination at all times and is subject to intermittent impacts to water quality from pollution sources. The status of a

Conditionally Restricted shellfish growing area may change from Open to Closed in response to such intermittent water quality impacts or other environmental conditions affecting water quality, including predictable changes in water quality. The harvest of shellfish from a Conditionally Restricted shellfish growing area is prohibited, except as provided at 322 CMR 16.03(2)(f).

(e) Prohibited. A Prohibited shellfish growing area has been subject to sanitary survey that demonstrates shellfish within the growing area contain contamination and pollutants at all times and pose a public health risk. The harvest of shellfish from a Prohibited shellfish growing area is prohibited, except as provided at 322 CMR 16.03(2)(f).

(f) Exceptions. The following activities may be conducted within shellfish growing areas that have been classified as contaminated and shellfish harvest is otherwise prohibited:

1. Contaminated Bait Fishery. A surf clam dredge contaminated bait fishery may be conducted in shellfish growing areas classified as Prohibited in accordance with 322 CMR 6.08(7).
2. Contaminated Shellfish Relay. Contaminated shellfish relays may be conducted in shellfish growing areas classified as Restricted, Conditionally Restricted and Prohibited and Conditionally Approved and in the Closed Status in accordance with 322 CMR 16.08.
3. Depuration Fishery. A depuration shellfish fishery may be conducted in shellfish growing areas classified as Restricted or Conditionally Restricted in the Open Status in accordance with 322 CMR 10.00: Management of Moderately Contaminated Shellfish.
4. Nursery Culture. The culturing and grow-out of hatchery seed may occur in shellfish growing areas classified as Restricted, Conditionally Restricted or Prohibited subject to the conditions set forth in a special project transplant permit issued in accordance with 322 CMR 7.01(4)(c): Special Project.

(3) Notification of Shellfish Growing Area Classifications. To ensure that the public is aware of the classification of all shellfish growing areas and to safeguard public health by protecting against the consumption of contaminated shellfish, the Division shall:

(a) Announce changes to existing shellfish growing area classifications in accordance with the public notification procedures set forth at M.G.L. c. 130, § 74A.

(b) Make available to the public a list of all shellfish growing areas, their boundaries and their classification on the Division's website at www.mass.gov/marinefisheries.

(c) Make available to the public maps depicting all shellfish growing areas and their classification on the Division's website at www.mass.gov/marinefisheries.

(4) Changes to Shellfish Growing Area Status. Changes to environmental conditions affecting water quality, or the presence of pollutants or toxins in such waters may render shellfish unfit for consumption and hazardous to public health.

(a) Designation of Contamination of Shellfish Growing Areas. In accordance with M.G.L. c. 130, § 74A, the Director may issue a designation of contamination (change of status) to prohibit the harvest of all or certain species of shellfish from any shellfish growing area.

(b) Status Changes to Conditionally Approved Shellfish Growing Areas Subject to a Local Conditional Area Management Plan. For those shellfish growing areas

classified as Conditionally Approved and subject to a Conditional Area Management Plan, the applicable municipality shall be responsible for providing public notification of any such status changes."

c. Record Keeping [Chapter I. @.01 C.]

The MA DMF meets the requirements of Chapter I @.01 C. The MA DMF maintains electronic and hard copy records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. The records are maintained in a central file (computer or file cabinets) at the DMF offices located in Gloucester, MA and New Bedford, MA and are available upon request.

d. Shared Responsibilities [Chapter I. @.01 D.]

The MA DMF does not meet the requirements of Chapter I. @.01 D. The MA DMF continues under a 2021 action plan for this deficiency. The administration of the MA shellfish sanitation program related to growing area classification is a shared responsibility between two (2) agencies; the MA Executive Office of Energy and Environmental Affairs (MA EOEEA) and the MA Department of Public Health (MA DPH). Two (2) divisions within the MA EOEEA, the Division of Marine Fisheries (MA DMF) and Office of Law Enforcement, (the MA Environmental Police (MA OLE)), and the MA DPH Food Protection Program (MA DPH) are involved in the administration of the statewide shellfish safety and sanitation program, shall have a memorandum of agreement (MOA) developed between the agencies to define each agency's responsibilities. Refer to section A. 3. for details.

e. Administrative Procedures [Chapter I. @.01 E.]

MA meets the requirements of Chapter I. @.01 E. The MA DPH has sufficient administrative procedures to ensure that all shellfish shipped in interstate commerce originate from certified dealers located within the state. The MA DPH does not have any MOA with other states to allow dealers from MA to purchase shellstock harvested and landed in another state. The MA DPH has the authority to embargo or condemn contaminated or adulterated shellfish products.

The MA DPH Food Protection Program is the lead agency for product recalls and has established a policy to recall contaminated shellfish. Based on 105 CMR 500.000, specifically, 105 CMR 500.200-213, the MA DPH is sanctioned to take any action necessary to prevent consumer illnesses by suspending or revoking interstate shipping permits and initiating embargoes of any potentially adulterated shellfish already on the market. The MA OLE carries out seizures and orders destructions, if necessary, pursuant to M.G.L. chap.130, §§ 9 and 12. The MA DPH assures compliance with shellfish plant inspection standardization.

f. Personnel training requirements for implementing the NSSP [Chapter I. @.01 H. (2) (a) (i-ii)

The MA DMF meets the requirements of Chapter I. @.01 H. (2) (a) (i – ii). The DMF has 11 growing area classification staff members that have completed the FDA growing area course (FD242) and has at least one (1) year of on-the-job experience to qualify as the sanitary survey officer.

g. Laboratory Element [Chapter III. @.01 and @.02]

There are currently three (3) MA DMF laboratories that conduct analyses to support the growing area classification program element in MA. The MA DMF's New Bedford (located at 706 South Rodney French Boulevard, New Bedford), Gloucester (located at 30 Emerson Avenue, Gloucester), and Newburyport (located at 84 82nd Street, Newburyport) laboratories. The New Bedford and Gloucester laboratories conduct coliform analyses of shellfish growing area waters using the membrane Thermotolerant E. coli (mTEC) fecal coliform method. The Gloucester laboratory performs the mouse bioassay (MBA) for paralytic shellfish poisoning (PSP) in shellfish meats. The Newburyport laboratory performs the Male Specific Coliphage for Soft-shelled Clams method.

The New Bedford and Gloucester laboratories were evaluated by the FDA in June 2016. The New Bedford laboratory was found to conform to the NSSP requirements. The Gloucester laboratory was found to conform for PSP testing and provisionally conform for the microbiological testing requirements. The CFSAN LEO conducted follow-up on deficiencies identified and documented after completion of the laboratory evaluations and issuance of the final checklists through a desk audit of documents submitted by the MA DMF Gloucester microbiological laboratory since the 2016 evaluation. On July 13, 2018, based on the documentation provided, the operational status of the Gloucester microbiological laboratory was upgraded from provisional to conforming under the NSSP. The Newburyport laboratory was evaluated by the (now retired) MA DMF LEO in June 2016. The laboratory was found to conform to the NSSP requirements.

In October of 2016, during an Amnesic Shellfish Poisoning (ASP) closure, the MA DMF purchased and used Scotia Rapid Test kits to screen shellfish meats and utilized the services of the Bigelow Laboratory for Ocean Sciences in Boothbay, Maine for High Performance Liquid Chromatography (HPLC) testing for domoic acid toxin in shellfish meats.

There are two (2) additional NSSP conforming laboratories in MA that provide support to the growing area classification program and were evaluated by the (now retired) MA DMF LEO. The New Bedford Public Health Department Laboratory (located at 1000 South Rodney French Boulevard) was evaluated by the MA DMF LEO on October 20, 2017. The laboratory predominantly performs the APHA Most Probable Number (MPN) testing for total coliforms for shellfish dealers with wet storage tanks. The lab is also capable of analyzing seawater samples using mTEC. The Massachusetts Water Resources Authority (MWRA) WWTP water quality lab on Deer Island in Winthrop was evaluated on April 20, 2018. The lab performs membrane filtration using mTEC on seawater in Boston Harbor. The data is used by MA DMF to supplement DMF data around the outfall of the MWRA plant.

The shellfish landings from Georges Bank in federal waters harvested and managed under the biotoxin management strategy of pre-harvest shellfish toxicity screening and lot testing (Chapter IV. @.04 B. (4) (e)) utilizes Abraxis Shipboard ELISA for screening and the PCOX at the Bigelow Laboratory for Ocean Sciences in Boothbay, Maine for lot testing. The FDA CFSAN LEO has the MA DMF and supporting laboratories evaluations on the FY2023 work schedule.

h. Sanitary Survey [Chapter IV. @.01. A. – C.]

The MA DMF meets the requirements of Chapter IV. @.01 A. (1) (a, b, and d) and completes a sanitary survey every 12 years in accordance with Chapter IV. @.01 C. The MA DMF does not meet the requirement of Chapter IV. @.01 A. (1) (c). Chapter IV @.01 A. (1) (c) requires the sanitary survey include the data and results of an evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area. The sanitary survey reports for BB10, BB12, and BB13 do not include the data and results of an evaluation of effect of meteorological and hydrodynamic effects in the section entitled 'meteorological and hydrographic effects' and there is no data, results, or evaluation of geographic characteristics on the growing area. The FDA is documenting this as a new or emerging concern; please refer to section B. 6. for additional details.

The MA DMF meets the requirements of Chapter IV. @.01 A. (3) by maintaining documentation supporting each sanitary survey in a central file that includes all data, results, and analyses per @.01 A. (3) (b and c), however, the sanitary surveys for BB10, BB12, and BB13 were not reviewed and signed by the sanitary survey officer pursuant to A. (3) (a). The FDA documented this as a new or emerging concern. The MA DMF corrected this new or emerging concern prior to issuance of the final report; please refer to section B. 3. and B. 6. for additional details.

The MA DMF meets the requirements of Chapter IV. @.01 A. (4) by maintaining a current comprehensive, list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area at Shellfish Classification Areas.

The MA DMF does not meet the requirements of Chapter IV. @.01 A. (2) because the following triennial reevaluations and annual reviews were not updated in accordance with Chapter IV. @.01 C. to assure that data are current and that conditions are unchanged. The MA DMF does not meet the requirements of Chapter IV. @.01 C. (3) (a) (ii) (new or emerging concern), @.01 C. (3) (a) (iii) (repeat deficiency from 2017 and 2018), @.01 C. (3) (a) (iv) (new or emerging concern), @.01 C. (5) (c) and (d) (new or emerging concern), and @.01 C. (6) (deficiency). Specifically, the FDA is documenting these as deficiencies and new or emerging concerns; please refer to section B. 4. and B. 6. for details. The deficiencies and new or emerging concerns by growing area are:

- BB10: The 2021 annual does not include a review of available inspection reports and effluent samples collected from pollution sources or of the available performance standards for the Dartmouth WWTP discharge that impacts the growing area (Chapter IV. @.01 C. (5) (c) and (d)).
- BB11:
    - The 2021 triennial does not include a reevaluation of the New Bedford WWTP (Chapter IV. @.01 C. (3) (a) (iii)).
    - The 2021 triennial and the 2021 annual do not include a review of available inspection reports and effluent samples collected from pollution sources or a review of available performance standards for the New Bedford and Dartmouth WWTP discharges that impact the growing area. (Chapter IV. @.01 C. (5) (c) and (d))
- BB13: the 2021 annual does not include a review of available inspection reports and effluent samples collected from pollution sources or a review of available performance standards for the New Bedford WWTP and CSO discharges that impact the growing area. (Chapter IV. @.01 C. (5) (c) and (d))

- BB22: There is no information in the annual or the triennial about the prohibited area BB22.1 expanding. There is no comprehensive report which analyzes the data and makes a determination that the existing growing area classification is correct or needs to be revised (Chapter IV. @.01 C. (3) (a) (iv)).
- BB25: The 2019 triennial identified and documented eight (8) new pollutions sources but there is not an evaluation of their effect on the growing area. (Chapter IV. @.01 C. (3) (a) (ii))
- BB31:
    - The 2019 triennial did not reevaluate all pollution sources previously identified in the sanitary survey (Chapter IV. @.01 C. (3) (a) (iii)). The 2013 sanitary survey documented ~77 boats and the 2019 triennial documented ~82 boats moored in Aucoot Cove but did not fully evaluate any changes in the sanitary condition of the growing area.
    - The 2019 triennial and the 2021 annual do not include a review of available inspection reports and effluent samples collected from pollution sources or of the available performance standards for the Marion WWTP discharge that impacts the growing area (Chapter IV. @.01 C. (5) (c) and (d)).
- BB32:
    - The 2020 triennial did not reevaluate all pollution sources previously identified in the sanitary survey (Chapter IV. @.01 C. (3) (a) (iii)). The >20 boats moored in Blankinship Cove and Planting Island Cove must be reevaluated.
    - There is no information in the annual or the triennial about the prohibited area BB32.15 expanding and absorbing BB32.1. There is no comprehensive report which analyzes the data and makes a determination that the existing growing area classification is correct or needs to be revised (Chapter IV. @.01 C. (3) (a) (iv)).
- BB36:
    - The 2019 triennial did not reevaluate all pollution sources previously identified in the sanitary survey and the mooring areas assessed in 2013 were not reevaluated in 2019 (Chapter IV. @.01 C. (3) (a) (iii)).
    - The 2019 triennial and the 2021 annual do not include a review of available inspection reports and effluent samples collected from pollution sources or a review of the available performance standards for the Wareham WWTP discharge that impacts the growing area (Chapter IV. @.01 C. (5) (c) and (d)).
- SC48, SC49, and SC50: The annual reviews were completed in January 2022 and determined that a portion of the approved area needed to be reclassified to conditionally approved due to mooring area(s). If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area (Chapter IV. @.01 C. (6)).

The MA DMF meets the requirements of Chapter IV. @.01 B. (1-2). Sanitary survey reports are not required to classify areas as prohibited but the findings of a sanitary survey may result in growing areas being classified prohibited. Sanitary survey, and triennial reevaluations, of each growing area are required prior to harvest of shellfish for

human consumption and for areas to be classified approved, conditionally approved, restricted, or conditionally restricted.

The MA DMF does not meet the requirements of Chapter IV. @.01 C. (1) because the sanitary survey reports for BB10, BB12, and BB13 'hydrographic and meteorological characteristics' section has no evaluation of effects of meteorological and hydrodynamic, and geographic evaluation of effects (Chapter IV. @.01 A. (1) (c)). The FDA is documenting this as a new or emerging concern. Refer to section B. 6. for details.

The MA DMF meets the requirements of Chapter IV. @.01 C. (2), C. (3) (a) (i) and (v), C. (3) (b), C. (5) (a) and (e).

i. Shoreline Survey Requirements [Chapter IV. @01. D.]

The MA DMF meets the requirements of Chapter IV. @.01 D. (1) (b), (d), and (f). The DMF does not meet the requirements of Chapter IV. @.01 D. (1) (a), (c), or (e) specifically:

- BB10: No assessment of the reliability or effectiveness of the Dartmouth WWTP (@.01 D. (1) (c)).
- BB11: No assessment of the reliability or effectiveness of the New Bedford or Dartmouth WWTPs (@.01 D. (1) (c)).
- BB13: No assessment of the reliability or effectiveness of the New Bedford WWTP (@.01 D. (1) (c)).
- BB21: There are four (4) aquaculture operations that must be assessed if they attract birds or mammals for possible adverse effects on water quality. (@.01 D. (1) (e))
- BB25: There is no evaluation of the effect of the >20 boats in Mattapoisett Harbor moored between BB25.12 and BB25.2 (@.01 D. (1) (a)).
- BB31: No assessment of the reliability or effectiveness of the Marion WWTP (@.01 D. (1) (c)).BB36:
    - There is no evaluation of the effect of the >20 boats moored in the Swifts Beach and Swifts Neck area. (@.01 D. (1) (a))
    - No assessment of the reliability or effectiveness of the Wareham WWTP (@.01 D. (1) (c)).
    - There are two (2) aquaculture operations that must be assessed to consider if they attract birds or mammals for possible adverse effects on water quality. (@.01 D. (1) (e))
- SC49: There is one (1) aquaculture operation that must be assessed to consider if they attract birds or mammals for possible adverse effects on water quality. (@.01 D. (1) (e))
- SC50: There is one (1) aquaculture operation that must be assessed to consider if they attract birds or mammals for possible adverse effects on water quality. (@.01 D. (1) (e))

The MA DMF will continue under the 2018 action plan for evaluating mooring areas (@.01 D. (1) (a)); refer to section A. 3. for details. The FDA is documenting the lack of assessment of the reliability or effectiveness of the WWTPs (@.01 D. (1) (c)) and the assessment of aquaculture operations (if they attract birds or mammals) (@.01 D. (1) (e)) as new or emerging concerns. Refer to section B. 6. for details.

The MA DMF meets the requirements of Chapter IV. @.01 D. (2) except for the Wareham WWTP outfall, which is not located on the comprehensive map of the survey area for BB36 (Chapter IV. @.01 D. (2) (d) (i)). The FDA is documenting this as a new or emerging concern; refer to section B. 6. for details.

j. Microbiological Standards [Chapter IV. @02.]

The MA DMF meets the requirements of Chapter IV. @.02 A. The DMF uses the fecal coliform (FC) standard to classify growing areas. The DMF uses male-specific coliphage (MSC) data in conjunction with bacteriological data to evaluate wastewater system discharge impacts to growing areas.

The MA DMF meets the requirements of Chapter IV. @.02 B. The number and location of sampling stations is adequate to effectively evaluate all pollution sources in the growing areas. The DMF also has sample stations located to effectively evaluate growing area waters over shellfish resources.

All the growing areas in MA are classified so no exceptions under Chapter IV. @.02 C. (1-3) apply.

The MA DMF uses adverse pollution condition (APC) for all growing areas. The geometric mean (geomean) (mTEC) shall not exceed 14 per 100 milliliters (ml) and not more than 10 percent (%) of the samples shall exceed 31 colony-forming units (CFU) per 100ml.

The MA DMF meets the requirements of Chapter IV. @.02 E. and F. The bacteriological water quality for each station in all growing areas evaluated met the appropriate requirements for their classification standard and sample frequency per NSSP MO. The FDA did not evaluate areas using the standards under Chapter IV. @.02 D., G., or H. The MA DMF has not identified a specific tidal stage that increases the fecal coliform concentration, so the exception to classify areas under that criterion does not apply (Chapter IV. @.02 F. (1)).

k. Growing Area Classification [Chapter IV. @03.]

The MA DMF meets the requirements of NSSP MO Chapter IV. @.03 A. (1). The MA DMF implements precautionary closures of shellfish growing areas in response to emergency conditions such as excessive rainfall in a 24-hour period in approved areas, flooding, hurricanes, oil or chemical spills, or any unpredicted pollution event that may threaten the quality of shellfish making them unsafe or potentially unsafe for human consumption.

The MA DMF meets the requirements of Chapter IV. @.03 A. (2.) (a.- b.). The growing areas evaluated found all areas were classified in conformance with NSSP MO.

The MA DMF meets the requirements of Chapter IV. @.03 A. (3). All MA growing area boundaries are delineated on maps with detailed boundary descriptions. The descriptions and maps can be accessed online at http://www.mass.gov/info-details/massgis-data-designated-shellfish-growing-areas. The Adobe PDF static maps can be accessed online at https://www.mass.gov/service-details/shellfish-classification-areas.

The MA DMF meets the requirements of Chapter IV. @.03 A. (4) (a – b). Any upward classification of a growing area is supported through an adequate sanitary survey. The FDA is notified via electronic mail of any revision in growing area classification.

The MA DMF meets the requirements of Chapter IV. @.03 A. (5) (a). The MA DMF maintains growing areas (except prohibited areas) in the open status, subject to the limitations of their classifications.

The MA DMF meets the requirements of Chapter IV. @.03 A. (5) (b) (i –v) by closing growing areas for a limited or temporary period for the reasons listed in @.03 A. (5) (b) (i-v).

The MA DMF does not meet the requirements of Chapter IV. @.03 A. (5) (d) (i) or (iii) for returning areas to the open status for emergency situations or conditions under a conditional area management plan (CAMP) (rainfall) (Chapter IV. @.03 C. (2) (iii)). The MA DMF does not have studies establishing sufficient lapsed time to document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studies may establish criteria for reopening based on coliform levels in the water. For rainfall CAMPs, the MA DMF is not sampling water to re-open but has automatic re-openings and no studies established to show criteria based for coliform levels in the water. This is a continued deficiency from 2016 - 2018 and will continue under an existing action plan. Refer to section A. 3. for details.

The MA DMF meets the requirements of Chapter IV. @.03 A. (5) (d) (ii). Emergency closures of growing areas caused by the occurrence of raw untreated sewage discharged from a WWTP and closures of WWTP conditional areas (Chapter IV. @.03 C. (2) (c) (iii)) are closed for 21 days after the contamination has ceased or shellfish samples are collected no sooner than seven (7) days after the contamination has ceased and the MSC levels meet the requirements of Chapter IV. @.02 E (must not exceed 50 male-specific coliphage (MSC)/100 grams).

The MA DMF meets the requirements of Chapter IV. @.03 A. (5) (d) (iii) for biotoxins as established in section @.04.

The MA DMF meets the requirements of Chapter IV. @.03 A. (5) (d) (iv). Supporting information for re-opening growing areas temporarily placed in the closed status is documented by written and electronic records in the central files.

The MA DMF does not have any growing areas in the controlled access, inactive, or seasonally remote and approved status (Chapter IV. @.03 A. (5) (c), (e), and (g)).

The MA DMF does not meet the requirements of Chapter IV. @.03 A. (5) (f). The DMF has 39 areas classified as approved in the remote status and most do not meet the NSSP definition of ‘remote status’ pursuant to Section I Definitions, B. (100) as being ‘a shellfish growing area that has no human habitation and is not impacted by any actual or potential pollution sources.’ The areas have human habitation in the form of coastal seasonal and year-round homes, private and state bathing beaches, golf courses, small airports or airfields, and inns. The FDA is documenting this as a new or emerging concern; refer to section B. 6. for details.

The MA DMF meets the requirements of Chapter IV. @.03 B. by having approved areas classified in accordance with the criteria in @.03 B. (1) and (2).

The MA DMF meets the requirements of Chapter IV. @.03 C. (1) by having growing areas classified as conditional that meet the criteria under C. (1) (a) – (d).

The MA DMF does not meet the requirements of Chapter IV. @.03 C. (2) as each growing area classified as conditional must develop a written management plan. The lack of written management plans is a continued deficiency from 2017-2018 and will continue under the 2018 action plan. Refer to section A. 3. for details. The following areas have conditional areas and no written management plan:

- BB11.3
- BB12.5
- BB25.2
- SC48.4, SC48.5, SC48.6, SC48.7, and SC48.8
- SC49.1, SC49.2, SC49.3, and SC49.4
- SC50.1
- SC51.1, SC51.2

The MA DMF does not meet the requirements of Chapter IV. @.03 C. (2) (a). The conditional area management plan (CAMP) for BB13 does not include performance standards for combined sewer overflows (CSOs). The FDA is documenting this as a deficiency as it was documented as a new or emerging concern in 2018. Refer to section B. 6. for details.

The MA DMF does not meet the requirements of Chapter IV. @.03 C. (2) (a) (viii). The CAMPs for WWTP conditional areas must include establishment of an area in the prohibited classification adjacent to a WWTP outfall in accordance with @.03 E. The prohibited areas for the Dartmouth WWTP in BB10, the Marion WWTP in BB31, and the Wareham WWTP in BB36 have no dilution analyses to show how the size of the prohibited areas were determined. The FDA is documenting this as a deficiency as it was documented as a new or emerging concern in 2018. The MA DMF provided dilution analyses for the three (3) WWTPs on August 15, 2022. Refer to sections B.3. and B.4. for details.

The MA DMF does not meet the requirements of Chapter IV. @.03 C. (2) (b) (ii). Management plans based on pollution sources other than WWTPs must contain discussion and data supporting the performance standard. The CAMP for BB13 does not have discussion and data supporting the performance standard of 0.5” rain in 24hrs BB13.1 and >2.0” rain in24hrs BB13.2. The CAMP for BB22.3 does not have discussion and data supporting the performance standard of 0.25” rain in 24 hours. The FDA is documenting this as a new or emerging concern. Refer to section B.6. for details.

The MA DMF does not meet the requirements of Chapter IV. @.03 C. (2) (c) (i – iv). CAMPs based on WWTP or pollution sources other than WWTP criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its CAMP can be returned to the open status when the minimum criteria under @.03 C. (2) (c) (i – iv) are met. The CAMPs for BB13 and BB22.3 do not contain re-opening criteria that meet the requirements of @.03 C. (2) (c) (i – iv). The FDA is documenting

this as a deficiency; it is a continued deficiency from 2016 - 2018 and will continue under an existing action plan. Refer to section A. 3. for details.

The MA DMF does not have any management plans based on a risk assessment or marine biotoxins pursuant to Chapter IV. @.03 C. (2) (d) and (e).

The MA DMF does not meet the requirement of Chapter IV. @.03 C. (2) (f). CAMPs must have procedures for immediate notification to the authority when performance standards or criteria are not met. The BB12.3 CAMP does not have procedures for immediate notification to the DMF when performance standards are not met (shellfish constable and harbormaster must report overboard discharges from vessels to the DMF and when the number of vessels exceeds the NSSP MO requirements before May 1 or after October 31). The BB13 CAMP notification procedure for the WWTP has them reporting immediately to the MA DPH and not the MA DMF. The FDA is documenting this as a new or emerging concern; refer to section B. 6. for details.

The MA DMF meets the requirements of Chapter IV. @.03 C. (2) (g – h).

The MA DMF meets the requirements of Chapter IV. @.03 C. (3), (4), and (5).

The MA DMF meets the requirements of Chapter IV. @.03 C. (6) (a) but does not meet the requirements of Chapter IV @.03 C. (6) (b). Chapter IV @.03 C. (6) (b) requires any growing area in the conditionally approved classification must designate in the CAMP whether the shellstock may be harvested for relaying or depuration if the closed status meets the criteria for restricted classification. None of the CAMPs evaluated included this statement. The FDA is documenting this as a new or emerging concern; refer to section B.6. for details.

The FDA did not evaluate any growing areas classified restricted during this evaluation (Chapter IV. @.03 D.).

The MA DMF meets the requirements of Chapter IV. @.03 E. (1). The DMF classifies some marina areas as prohibited and some as conditionally approved.

The MA DMF meets the requirements of Chapter IV. @.03 E. (3) and (4). All prohibited areas are supported by sanitary surveys and no areas are classified because of a risk assessment performed in accordance with Chapter II.

The MA DMF meets the requirements of Chapter IV. @.03 E. (5) (a). The MA DMF does not meet the requirements of Chapter IV. @.03 E. (5) (b). Wastewater discharges must have a determination of the size of the area to be classified as prohibited adjacent to each outfall that includes the minimum criteria in @.03 E. (5) (b) (i – iv). The WWTPs in BB10 (New Bedford), BB11 (Dartmouth), BB13 (New Bedford and Dartmouth), BB31 (Marion), and BB36 (Wareham) do not have documentation to show how the size of the prohibited classification was determined. This is a continued deficiency from 2017 - 2018 and will continue under an existing action plan. The MA DMF provided dilution analyses for the WWTPs in BB10, BB31, and BB36 on August 15, 2022. Refer to section A. 3. and B. 3. for details.

I. Marine Biotoxin Evaluation [Chapter IV. @.04]

i. Contingency Plan (@.04 A.):

The MA DMF does not meet the requirements of Chapter IV. @.04 A. (1). Chapter IV. @.04 A. (1) requires the authority develop and adopt a marine biotoxin contingency plan addressing the management of paralytic shellfish poisoning (PSP), diarrhetic shellfish poisoning (DSP), amnesiac shellfish poisoning (ASP), neurotoxic shellfish poisoning (NSP) and azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred, or an illness outbreak caused by marine biotoxins (i.e., that are not already covered under the biotoxin management plan). The 2022 update of the Massachusetts Marine Biotoxin Management Plan & Contingency Plan, Table 1. Biotoxin Action Levels and HAB Response Matrix in section HAB Response Thresholds and Biotoxin Action Levels [1] [2] states "[1]Procedures for AZP are to be considered as the Contingency Plan for these causative organisms and syndromes in all waters of the Commonwealth." The DMF has not developed and adopted a contingency plan that defines the administrative procedures and resources necessary to accomplish the requirements under Chapter IV. @.04 A. (2) (a – g). The FDA is documenting this as a new or emerging concern. Refer to section B. 6. for details.

ii. Marine Biotoxin Management Plan (@.04 B.):

The MA DMF does not meet the requirements of Chapter IV. @.04 B. (1) – (5). Chapter IV. @.04 B. requires the authority to develop and adopt a marine biotoxin management plan for all shellfish growing areas with a history of biotoxin closures related to PSP, ASP, NSP, DSP, and/or AZP; if toxin-producing phytoplankton have been documented to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur. The DMF management plan is specific to PSP and the plan must be updated to include ASP, NSP, and DSP. The plan must clearly define which management strategies the DMF are or are not using under @.04 B. (4) (a – e) for ASP, NSP, and DSP. The plan shall include agreements or MOU between the authority, individual shellfish harvesters, individual growers, or individual shellfish dealers, to allow harvesting in controlled access status growing areas under @.04 B. (4) (e) and B. (5). The plan must include administrative procedures and resources necessary to ensure that all shellfish harvested from controlled access status growing areas meet all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing, or product holds under Chapter IV. @.04 B. (2) (h). The FDA is documenting this as a new or emerging concern. Refer to section B.2.I. iii. and B. 6. for details.

iii. Closed or Controlled Access of Growing Areas (@.04 C.):

The MA DMF meets the requirements of @04 C. (1 – 6). The DMF will close growing areas or portion(s) of growing areas based on the biotoxin

concentration in shellfish meats based on the criteria for PSP, DSP, ASP, NSP, and AZP in accordance with the requirements under Chapter IV. @.04 C. (1) (a-e). The MA MBCMP includes phytoplankton screening for any marine biotoxin for which criteria have not been established under the MO, either cell counts of the toxin producing organism in the water column or biotoxin meat concentrations may be used as the criteria for not allowing the harvest of shellstock (@.04 C. (2)). Precautionary closures are implemented when phytoplankton monitoring indicates a problem, and the closures remain in place pending shellfish toxicity results (J. Kennedy, personal communication, September 27, 2022). The MA DMF has not employed an approach to exempt certain shellfish species from the closed status for harvesting under @.04 C. (3) without toxicity testing demonstrating a specie is below mandatory closure standards. The DMF closes areas and shellfish species based on our primary sentinel specie blue mussels for an area, waterbody, or region, or on a secondary station and shellfish species such as softshell clams. The DMF has historical data with PSP which has informed their current policies and approach. The approach may change in the future with the proliferation of aquaculture but currently for example, if mussel toxicity in Plymouth Harbor indicates a closure is needed, they will institute a closure for all shellfish species within the 3-bay system (Plymouth, Duxbury, Kingston). The reopening of areas and shellfish species is often staged by species in certain areas or regions and rely on phytoplankton monitoring to judge if a bloom is building or abating (J. Kennedy, personal communication, September 27, 2022). The closed status remains in effect until the DMF has data to show that the toxin content of harvestable species in the growing area are below the levels established for the area under @.04 C. (1). The DMF considers toxicity in shellfish in adjacent areas prior to returning an area to the open status (@.04 C. (5)) and adequately documents the analysis upon which they base a decision to return an area to the open status (@.04 C. (6)).

The MA DMF doesn't have any state growing areas, or portions thereof, in the controlled access status under @.04 C. (7).

The MA DPH oversees a program under an NSSP Protocol for the Landing of Shellfish from Federally Closed Waters due to PSP. The activity allows the harvest and landing of surf clams and ocean quahogs from the waters of Georges Banks which are in the controlled access status as determined by the FDA and NOAA in accordance with marine biotoxin management strategies under Chapter IV. @.04 B. (4) (e). The MA DPH and the MA DMF do not meet the requirements of Chapter IV. @.04 B. (5). The MA marine biotoxin management plan shall include agreements or memoranda of understanding, between the authority(ies) and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in a growing area that is placed in the controlled access status. Shellstock harvested from a growing area, or portion(s) thereof, placed in the controlled access status for the taking of shellstock shall be tagged with restricted shellstock tags that meet the requirements of Chapter X .05 E. The plan must include administrative procedures and resources necessary to ensure that all shellfish harvested from controlled access status growing areas meet all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing, or product holds under Chapter IV. @.04

B. (2) (h). The FDA is documenting this as a new or emerging concern. Refer to section B. 2. l. ii. and B.6. for details.

iv. Heat Processing (@.04 D.):

MA does not have any firms practicing heat processing.

v. Records (@.04 E.):

The MA DMF meets the requirements of @.04 E. by maintaining all monitoring data, copies of closure notices, evaluation reports, and re-opening notices.

m. Marinas [Chapter IV. @.05]

The MA DMF meets the requirements of Chapter IV. @.05 A. (1). The DMF has areas within marinas, in or adjacent to shellstock growing areas, classified conditionally approved or prohibited. Marina areas classified conditionally approved are supported by a pollution assessment.

The MA DMF does not meet the requirements of Chapter IV. @.05 B. The marina prohibited area in BB25, and the marina conditionally approved areas in SC48 and SC49 must have a dilution analysis to determine if there is any impact to adjacent waters. The FDA is documenting this as a new or emerging concern. Refer to section B.6. for details.

n. Mooring Areas [Chapter IV. @.06]

The MA DMF does not meet the requirements of Chapter IV. @.06 A. (1) and (3). The FDA is documenting this as a new or emerging concern. Refer to section B. 6. for details. The area within any designated mooring area, where there is an anchoring of boats, which is in or adjacent to a shellstock growing area shall be classified conditionally approved, conditionally restricted, restricted, or prohibited. The mooring areas and anchorages in approved growing areas:

- BB25 – the >20 boats between BB25.12 and BB25.2.
- BB31 – the >20 boats in BB31.0.
- BB32 – the >20 boats in BB32.0 (Blankinship Cove and Planting Island Cove).
- BB36 – the two (2) areas with >20 boats in BB36.0 off Swifts Beach and Swifts Neck.

The MA DMF does not meet the requirements Chapter IV. @.06 A. (2). Mooring areas that have been assessed and determined not to be a pollution source should not be placed in the open status until it is documented in a CAMP. The mooring areas assessed and determined not to be a pollution source and in the open status are BB12.5, BB25.2, SC48.7, SC48.8, SC49.1, SC49.2, SC49.3, SC49.4, SC50.1, SC51.1, and SC51.2. The areas do not have conditional area management plans and should not be in the open status. The FDA is including this citation with the existing action plan for the Chapter IV. @.03 C. (2) that requires each growing area classified as conditional must develop a written management plan. Refer to section A. 3. for details.

The MA DMF does not meet the requirements of Chapter IV. @.06 B. Waters adjacent to mooring areas that have been assessed and determined a pollution source require a

dilution analysis to determine if there is any impact to adjacent waters. The mooring areas in BB12.3, BB25.2, BB32.13, and BB36.14 must have a dilution analysis conducted to determine impacts to adjacent waters. The FDA is documenting this as a new or emerging concern. Refer to section B. 6. for details.

3. Corrective Actions Taken by State

On August 11, 2022, the MA DMF provided title pages for the BB10, BB12, and BB13 sanitary survey reports reviewed and signed by the sanitary survey officer to address the new or emerging concern in section B. 6 (Chapter IV. @.01 A. (3) (a)).

On August 15, 2022, the MA DMF provided dilution analyses to show how the size of the area to be classified prohibited adjacent to the Dartmouth, Marion, and Wareham WWTPs was determined for BB10, BB31, and BB36, respectively. The DMF used the FDA volumetric dilution calculator that includes the minimum criteria in Chapter IV. @.03 E. (5) (b) (i – iv).

4. Action Plan(s)

The FDA requests a corrective action plan for the Chapter IV. @.01 C. (6) deficiency. The action plan must include a detailed description of how the item was corrected or how the authority proposes to correct the deficiency. No action plan is required for the second deficiency (Chapter IV. @.03 C. (2) (a) (viii)) because the MA DMF addressed it before the report was finalized. The action plan must include a completion date or a timeline for completion of corrections, respectively, within 30 days of receipt of the final PEER.

No.	Deficiency
1.	Chapter IV. @.01 C. (6) requires if the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area. The SC48, SC49, and SC50 annual reevaluations determined that portions of the approved areas needed to be reclassified to conditionally approved due to mooring area(s). The determination was made in January 2022 and the areas were reclassified July 1, 2022. Refer to section B. 2. h. for details.
2.	Chapter IV. @.03 C. (2) (a) (viii) requires CAMPs for WWTP conditional areas include establishment of an area in the prohibited classification adjacent to a WWTP outfall in accordance with @.03 E. The prohibited areas for the Dartmouth WWTP in BB10, the Marion WWTP in BB31, and the Wareham WWTP in BB36 have no dilution analyses to show how the size of the prohibited areas were determined. The FDA is documenting this as a deficiency as it was documented as a new or emerging concern in 2018. Refer to section B.2.k. for details. **The MA DMF provided dilution analyses for the WWTPs in BB10, BB31, and BB36 on August 15, 2022, to correct this deficiency; refer to section B. 3. for details.**

5. State Program Accomplishments

The MA DMF was proactive in addressing one (1) of the deficiencies and one (1) of the new or emerging concerns identified during the evaluation.

The MA DMF has made significant progress on the 2016-2018 action plans by resolving five (5) deficiencies.

<<please provide program accomplishments>>

6. New or Emerging Concerns

The FDA identified the following new or emerging concerns during the evaluation.

No.	New or Emerging Concerns
1.	Chapter IV. @.01 A. (1) I requires the sanitary survey include the data and results of an evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area. The sanitary survey reports for BB10, BB12, and BB13 do not include the data and results of an evaluation of effect of meteorological and hydrodynamic effects in the section entitled 'meteorological and hydrographic effects' and there is no data, results, or evaluation of geographic characteristics on the growing area. Refer to section B. 2. h. for details.
2.	Chapter I. @.01 A. (3) (a) requires sanitary surveys be reviewed and signed by the sanitary survey officer as defined under Chapter I. @.01 H. (2) (a) (i -ii). The sanitary surveys for BB10, BB12, and BB13 were not reviewed and signed by the sanitary survey officer; refer to section B. 2. h. for details. **The MA DMF corrected this new or emerging concern; refer to section B. 3. for details.**
3.	Chapter IV. @.03 C. (2) (a) requires that management plans based on wastewater treatment plant function include performance standards listed under @.03 C. (2) (a) (i – viii). The BB13 CAMP requires performance standards for the CSOs discharging to the growing area. Refer to section B.2.k. for details.
4.	Chapter I. @.01 C. (3) (a) (ii) requires the triennial reevaluation to include documentation of any new pollution sources and an evaluation of their effect on the growing area. The 2019 triennial for BB25 identified and documented eight (8) new pollution sources but there is not an evaluation of their effect on the growing area. Refer to section B.2.h. for details.
5.	Chapter I. @.01 C. (3) (a) (iv) requires the triennial reevaluation to include a comprehensive report which analyzes the sanitary survey data and makes a determination that the existing growing area classification is correct or needs to be revised. There is no information in the annual report or the triennial reevaluation for BB21 about the expansion of the prohibited area BB22.1. There is no information in the annual report or the triennial reevaluation for BB32 about the expansion of the prohibited area BB32.15 and inclusion of BB32.1. Refer to section B.2.h. for details.
6.	Chapter IV. @.01 C. (5) (c) and (d) requires (on an annual basis) the review of available inspection reports, effluent samples collected from pollution sources, and available performance standards for various types of discharges that impact the growing area. The BB10, BB11, BB13, BB31, and BB36 annual reports and triennial reevaluations do not include a review of available performance standards for various types of discharges that impact the growing area; New Bedford, Dartmouth, Marion, and Wareham WWTPs, respectively. Refer to section B. 2. h. for details.
7.	Chapter IV. @.01 D. (1) (c) requires an assessment of the reliability and effectiveness of sewage or other waste treatment systems. The Dartmouth, New Bedford, Marion, and Wareham WWTPs reliability and effectiveness must be assessed in growing areas BB10, BB11, BB13, BB31, and BB36. Refer to section B. 2. i. for details.

No.	New or Emerging Concerns
8.	Consistent with Chapter IV. @.01 D. (1) (e), when aquaculture as defined in the MO attracts birds or mammals, their presence should be considered for possible adverse effects on growing area water quality in growing areas BB21, BB36, SC49, and SC50. Refer to section B.2.i. for details.
9.	Chapter IV. @.01 D. (2) (d) (i) requires the location of the site for each pollution source identified by the authority as affecting a growing area on a comprehensive map of the survey area. The Wareham WWTP outfall is not located on the comprehensive map of the survey area for BB36. Refer to section B. 2. i. for details.
10.	Chapter IV. @.03 A. (5) (f) allows a growing area to be placed in the remote status if the sanitary survey determines the area has no human habitation and is not impacted by any actual or potential pollution sources. Most of the 39 growing areas classified as approved in the remote status do not meet the NSSP definition of 'remote status' nor do they meet the requirements of Chapter IV. @.03 A. (5) (f) because the areas have human habitation. Refer to section B. 2. k. for details.
11.	Chapter IV. @.03 C. (2) (b) (ii) requires CAMPs for conditional areas based on pollution sources other than WWTPs to contain discussion and data supporting the performance standards. The CAMP for BB13 does not have discussion and data supporting the performance standard of 0.5" rain in 24hrs BB13.1 and >2.0" rain in 24hrs BB13.2. The CAMP for BB22.3 does not have discussion and data supporting the performance standard of 0.25" rain in 24 hours. Refer to section B.2.k. for details.
12.	Chapter IV. @.03 C. (2) (f) requires CAMPs have procedures for immediate notification to the authority when performance standards or criteria are not met. The BB12.3 CAMP does not have procedures for immediate notification to the DMF when performance standards are not met (shellfish constable and harbormaster must report overboard discharges from vessels to the DMF and when the number of vessels exceeds MO requirements before May 1 or after October 31). The BB13 CAMP notification procedure for the WWTP has them reporting immediately to the Department of Health and not the DMF. Refer to section B.2.k. for details.
13.	Chapter IV. @.03 C. (6) (b) requires any growing area in the conditionally approved classification must designate in the CAMP whether the shellstock may be harvested for relaying or depuration if the closed status meets the criteria for restricted classification. None of the CAMPs evaluated included this statement. Refer to section B.2.k. for details.
14.	Chapter IV. @.05 B. requires a determination if there is any impact by pollution associated with the marina on waters adjacent to marina waters classified conditionally approved or prohibited. The marina prohibited area in BB25, and the marina conditionally approved areas in SC48 and SC49 must have a dilution analysis to determine if there is any impact to adjacent waters. Refer to section B.2.m. for details.
15.	Chapter IV. @.06 A. requires that areas within any designated mooring area, where there is an anchoring of boats, which is in or adjacent to a shellstock growing area shall be classified conditionally approved, conditionally restricted, restricted, or prohibited. There are >20 boats moored in the approved area between BB25.12 and BB25.2. There are ~20 boats moored in the approved area in BB31.0 (assess and monitor) There are >20 boats in the approved area in BB32.0 (Blankinship Cove and Planting Island Cove). There are two (2) areas with ~20 boats in the approved area in BB36.0 off Swifts Beach and Swifts Neck (assess and monitor). Refer to section B.2.n. for details.

No.	New or Emerging Concerns
16.	Chapter IV. @.06 B. requires a dilution analysis to determine if there is any impact to waters adjacent to mooring areas that have been assessed and determined to be a pollution source. The mooring areas in BB12.3, BB25.2, BB32.13, and BB36.14 must have a dilution analysis conducted to determine impacts to adjacent waters. Refer to section B. 2. n. for details.
17.	Chapter IV. @.04 A. (1) requires the authority develop and adopt a marine biotoxin contingency plan addressing the management of PSP, ASP, NSP, DSP, and AZP in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred, or an illness outbreak caused by marine biotoxins (i.e., that are not already covered under the biotoxin management plan). The 2022 update of the Massachusetts Marine Biotoxin Management Plan & Contingency Plan, Table 1. Biotoxin Action Levels and HAB Response Matrix in section HAB Response Thresholds and Biotoxin Action Levels [1] [2] states "[1]Procedures for AZP are to be considered as the Contingency Plan for these causative organisms and syndromes in all waters of the Commonwealth." The DMF has not developed and adopted a contingency plan that defines the administrative procedures and resources necessary to accomplish the requirements under Chapter IV. @.04 A. (2) (a – g).
18.	Chapter IV. @.04 B. (1) – (5) requires the authority to develop and adopt a marine biotoxin management plan for all shellfish growing areas with a history of biotoxin closures related to PSP, ASP, NSP, DSP, and/or AZP; if toxin-producing phytoplankton have been documented to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur. The present DMF management plan is specific to PSP and the plan must be updated to include ASP, NSP, and DSP. The plan must clearly define which management strategies the DMF are/are not using under @.04 B. (4) (a – e) for ASP, NSP, and DSP. The plan shall include agreements or MOU between the authority, individual shellfish harvesters, individual growers, or individual shellfish dealers, to allow harvesting in controlled access status growing areas under Chapter IV. @.04 B. (4) (e) and B. (5). The plan must include administrative procedures and resources necessary to ensure that all shellfish harvested from controlled access status growing areas meet all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing, or product holds under B. (2) (h).

7. Technical Assistance and/or Training Requested by the State

   The MA DMF requested five (5) to seven (7) newly hired staff members attend the next offering of FD242 Sanitary Surveys of Shellfish Growing Areas, April 10-14, 2023.

   The FDA offered to provide technical assistance via quarterly conference calls with the MA DMF staff members regarding any topic requested.

   On July 28, 2020, the MA DMF submitted a GARB request entitled "Hydrographic Dye Study of the Scituate Massachusetts WWTP in the North River" in the MB5 and MB6 growing areas. Due to COVID-19 travel restrictions, the study has not been scheduled.

   <<please provide technical assistance and training requests>>

8. Summary of the State's Response to FDA Evaluation

   <<please provide the state's response>>

9. Conclusion

The FDA's FY2022 growing area classification program element evaluation identified two (2) program deficiencies. The DMF corrected one (1) of the deficiencies before the evaluation report was issued. The FDA documented 18 new or emerging concerns and corrective actions were taken immediately to address one (1) of these concerns. The FDA is requesting an action plan from the MA DMF because of this evaluation for one (1) deficiency. The next program element evaluation will be conducted in FY2023.

10. FDA Recommendations

The FDA recommends:

No.	Recommendations
1.	The growing area reports document when sample stations have been added but not when they are archived. Documenting the date or year a sample station is archived completes a history of the growing area and accounts for changes in sample stations.
2.	Appropriate use of defined terms in the NSSP MO. Specifically, the description of aquaculturist activities in the SC50 triennial re-evaluation refers to husbandry activities as "relay".
3.	Develop templates for reports and conditional area management plans for consistency, uniformity, standardization, and compliance with the NSSP.
4.	The DMF conduct a dilution analysis for shellfish growing areas in the conditionally approved or approved classification adjacent to mooring areas classified conditionally approved and in the open status to determine if, in the event of an overboard discharge and a closure, if the adjacent area is impacted. An example would be the approved area adjacent to the conditionally approved/open status mooring area BB12.5.

11. Acknowledgements

The FDA wishes to thank MA DMF Director Dan McKiernan, Shellfish Program Lead, Jeff Kennedy, Senior Shellfish Biologist Matt Camisa, Senior Aquaculture Biologist Chrissy Petitpas, Laboratory Supervisor Brianne Shanks, and Shellfish Area Biologists John Mendes, Terry O'Neil, Simone Wright, Holly Williams, and Kaley Towns for their assistance with the information used to prepare this report.

12. Attachment(s)

Attachment 1. MA_20211006 MDMF Mooring Area Inventory (2 pages)

U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OSCP DIVISION OF SHELLFISH SANITATION

SENT VIA ELECTRONIC MAIL

September 30, 2022

Mr. Michael J. Moore, R.S., Director
Massachusetts Department of Public Health
Bureau of Environmental Health, Food Protection Program
305 South Street
Jamaica Plain, MA 02130

Mr. Jeff Kennedy
Shellfish Program Lead
Massachusetts Division of Marine Fisheries
30 Emerson Avenue
Gloucester, MA 01930

Re: FY2022 Chapter II Risk Assessment and Risk Management Program Element Evaluation Report

Dear Mr. Moore, and Mr. Kennedy,

The Food and Drug Administration (FDA) has completed the FY2022 evaluation of the Massachusetts (MA) Chapter II Risk Assessment and Risk Management (RARM) program element for shellfish, administered by the MA Department of Public Health (DPH), Bureau of Environmental Health, Food Protection Program, the MA Division of Marine Fisheries (DMF) and the MA Office of Law Enforcement (OLE). Enclosed is the FDA FY2022 Program Element Evaluation Report (PEER) describing the findings of the evaluation as determined from file reviews and field observations.

The FY2022 Chapter II Risk Assessment and Risk Management program element evaluation did not identify any new program deficiencies. The FDA is not requesting a new action plan because of this evaluation. The MA DPH will continue on the 2018 action plan for the continued deficiency related to the following: One (1) out of three (3) original shellfish dealers visited had Hazard Analysis Critical Control Point (HACCP) plans that were not in compliance with the 2022 MA *Vibrio parahaemolyticus* (Vp) Control Plan (CP) and did not contain all of the required critical limits for Vp [Chapter X.01 C.(3)].

The MA DPH, MA DMF, and MA OLE will continue to operate under the existing action plan cited in the MA Growing Area Classification, Plant Processing and Shipping, and Control of Harvest PEERs to demonstrate how compliance with the requirement for agencies (the MA DMF, the MA OLE, the MA DPH) having shared responsibilities for the administration of the statewide shellfish program, enter a MOA defining each participant's NSSP responsibilities pursuant to Chapter I @.01 D.

The FDA identified two (2) new or emerging concerns and made three (3) recommendations. The FDA will conduct a follow-up evaluation in FY2023.

If you should have any questions for me, please feel free to contact me at (305) 816-1456 or Michael.Lombardi@fda.hhs.gov. If you have any questions regarding this report, please do not hesitate to

U.S. Food & Drug Administration
RP-MIA4 RM01-04 HFR-SE2560
15100 NW 67th Avenue, Suite 400
Miami FL 33014-2048

contact David Lamoureux, Jr. at (781) 587-7441 or David.Lamoureux@fda.hhs.gov. I look forward to continuing the close working relationship between the FDA and the Massachusetts Department of Public Health (DPH), Division of Marine Fisheries (DMF), and Office of Law Enforcement (OLE).

Sincerely,

Michael C. Lombardi
Director, Shellfish Sanitation Branch II
Office of State Cooperative Programs
United States Food and Drug Administration

eCC: FDA CFSAN: F. Burditt, E. Elliot
FDA OSCP: A. Fitzpatrick, D. Lamoureux Jr., G. Wolf, Y. Sun, T. Deatrick
MA DPH: E. Hickey
MA DMF: C. Petitpas

ML/dml

FY2022
PROGRAM ELEMENT EVALUATION REPORT

OF THE

RISK ASSESSMENT AND RISK MANAGEMENT ELEMENT

EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS
DIVISION OF MARINE FISHERIES
AND
DEPARTMENT OF PUBLIC HEALTH
FOOD PROTECTION PROGRAM
OF THE
COMMONWEALTH OF MASSACHUSETTS

PREPARED BY

DAVID M. LAMOUREUX, JR.
SHELLFISH SPECIALIST
FDA OFFICE OF STATE COOPERATIVE PROGRAMS

ON

SEPTEMBER 30, 2022

PROGRAM ELEMENT EVALUATION REPORT

STATE: Massachusetts (MA)

PROGRAM ELEMENT EVALUATED: Risk Assessment and Risk Management

FREQUENCY OF EVALUATION: Annual

DATES OF EVALUATION: July 18-July 22, and July 28, 2022

TIME PERIOD UNDER REVIEW: The evaluation consisted of a review of illness data and information for the period of May 2021- July 2022, a review of the 2022 *Vibrio vulnificus* and *Vibrio parahaemolyticus* (Vp) risk assessments, and the 2022 Vp Control Plans (VpCPs). An in-field evaluation was conducted in July 2022.

A. Status of Previous Program Evaluation

a. Summary of Deficiencies from 2018, 2019 PEERs

The 2020-2021 evaluation of the MA Vibrio Risk Management Plan/Implementation (VRMP) evaluation efforts administered by the MA Division of Marine Fisheries (DMF) and the MA Department of Public Health (DPH) did not comply with requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The MA DMF and MA DPH continued to implement the 2018 action plan for deficiencies related to the following: original shellfish dealers visited had Hazard Analysis Critical Control Point (HACCP) plans that were not in compliance with the MA VpCP and did not contain all of the required critical limits for Vp [Chapter X.01 C.(3)]; and harvesters were making their own ice used to rapidly cool shellstock at their private homes and the harvester's private homes are not subject to inspection to determine that the ice is manufactured in accordance with the requirements under NSSP MO Chapter XI.02 A.(2) per NSSP MO Chapter IX.01 E.

b. State Action(s) to Correct Deficiencies from 2018, 2019 PEERs

On May 6th and 7th, 2019, the MA DMF and MA DPH provided an action plan to correct the two (2) deficiencies that have been documented and under an action plan since the 2018 evaluation. The MA DPH's plan included the following actions:

- The annual MA DPH email notification to announce the 2020 MA *Vibrio parahaemolyticus* Control Plan (VpCP) distributed to MA shellfish dealers, would advise dealers to implement the 2020 VpCP and update their HACCP plans accordingly, specifically, dealers would be advised to identify critical control points, identify critical limits, and conduct required monitoring in accordance with the 2020 MA VpCP. The announcement, sent May 19, 2020, included a vibrio HACCP plan template, the 2020 MA VpCP, and a vibrio monitoring record template.
- The MA DPH stated they would verify compliance during routine NSSP inspections and VpCP compliance inspections.

The MA DMF's action plan stated that they had updated their regulations (322 CMR 16.04 Sanitary Post-harvest Icing of Shellfish).

On August 31, 2020, the MA DMF sent an email to all who reported to the DMF that they use ice made by a privately owned and operated ice machine at their place of business or residence to cool shellfish for commercial sales, as required by the Vibrio Control Plan, and per the requirements pursuant to 322 CMR 16.04. The email contained information about MA DMF plans to add an ice course form to the vibrio logbook for 2022 that must be returned before the start of the VpCP season. The vibrio logbook is distributed by the local shellfish constables to all oyster harvesters and the DMF is hoping to get more responses from wild harvesters because of the effort. (C. Petitpas, personal communication, September 24, 2021).

c. Status of Action Plan(s)

The Food and Drug Administration's Office of Regulatory Affairs (ORA), and Center for Food Safety and Applied Nutrition (CFSAN) reviewed the action plan submitted by MA DPH and MA DMF on July 8, 2019 and accepted the proposed corrections via email on August 2, 2019. The MA DPH and MA DMF continue under the action plan to fully address HACCP plan critical limits at the MA certified dealers.

d. FDA Follow-up Regarding Previous PEER(s) Deficiencies and/or Action Plan(s)

The FDA followed up on both deficiencies during the FY2022 evaluation. The FDA found that one (1) dealer's HACCP plan did not have critical limits at the receiving critical control point to implement the 2022 MA VpCP critical limits for receiving. The FDA will monitor the status of the current action plan during the next in-field program element evaluation.

The deficiency related to ice machines located at harvesters' private residences was followed up on by the FDA during the 2022 evaluation. The MA DMF requires per their Private Shellfish Aquaculture Application Form that the source of ice must be disclosed by the applicant and provide information related to:

- Where they obtain their ice,
- Where the private residence ice machine is (address),
- Make and model of ice machine (must send DMF schematics from manual),
- If private residence, source of water,
- Include a copy of water quality test results conducted in the past 6 months that shows the source complies with drinking water quality standards at 310 CMR 22.00,
- Record of when machine is cleaned.

The MA DMF provided documentation and records for harvesters using ice from private residences to the FDA. The deficiency has been addressed by the MA DMF. The FDA will continue to monitor this during the next evaluation to confirm that harvesters are adhering to the MA DMF application requirements and compliance with 310 CMR 22.00.

B. Status of Current Evaluation

1. Current Findings

a. Administration [Chapter I @.01 A.]

The Commonwealth of MA has the statutory authority to address the eight (8) items listed under the Scope of the Authority [Chapter I@.01] and specifically the MA DPH is responsible for Chapter I @.01 A. (1.) (c. – g.). The MA DMF is responsible for Chapter I @.01 A. (1.) (a., b., and h.).

The MA DMF is the lead agency in administering any growing area closures related to outbreaks due to shellfish related illness, conducting the annual Vp and *Vibrio vulnificus* (Vv) risk evaluation, developing the annual production assessment, developing the VpCP, developing and providing training to wild harvesters and aquaculturists, and collecting environmental data to assess vibrio risk in harvesting areas. The MA DPH is the lead agency for investigating illnesses, developing the annual vibrio illness assessment, assisting the DMF with development of the VpCP related to certified dealers HACCP plans, and developing and providing training to dealers. The MA DMF laboratories support the Vibrio program through research.

b. State Laws and Regulations [Chapter I @.01 B.]

The MA Office of Law Enforcement (OLE), MA DMF, and MA DPH have not adopted the NSSP MO into law and therefore maintain their own laws and regulations to provide an adequate legal basis for the safe and sanitary control of all program elements including but not limited to the elements outlined in Chapter I @.01 A. The state laws and regulations that provide the legal basis for the vibrio control plan consistent with the NSSP MO are discussed below.

i. Statutes/Laws:

The state laws and regulations that provide the legal basis for the control of harvest, management of growing areas, shellstock relay, and shellfish aquaculture consistent with the NSSP MO include:

Massachusetts General Laws (M.G.L.):

Title XIV, Chapter 90B: MOTORBOATS, OTHER VESSELS AND RECREATIONAL VEHICLES

M.G.L. ch.90B §5C Discharge of sewage into waters designated as a no discharge area; fine; Any person that discharges sewage, whether treated or not, from a marine sanitation device into any waters of the commonwealth designated by the secretary of environmental affairs as a no discharge area pursuant to 33 U.S.C. 1322 shall be punished by a fine not to exceed $2,000 for each violation of this section.
M.G.L. ch.90B §12 Enforcement of chapter; The provisions of this chapter and all rules and regulations made under the authority thereof shall be enforced by the director, deputy directors of enforcement, chiefs of enforcement, deputy chiefs of enforcement, environmental police officers and deputy environmental police officers of the division of law enforcement, department of fisheries, wildlife and environmental law enforcement, by harbor masters and assistant harbor masters, by police officers assigned to harbor patrol, by fish and game wardens, by members of the state police, and by city and town police officers assigned to patrol the waters of the commonwealth. For the purpose of such enforcement such officers may board any motorboat and may conduct an inspection thereof, including an examination of the certificate of number, and may require the operator of such motorboat to give his true and correct name and address.

Whoever attempts to prevent any such officer from boarding such motorboat for the purpose of inspecting, or whoever attempts to prevent such officer from making an inspection of such boat, shall be punished as provided in section thirty-eight.

Title XIX, Chapter 130: MARINE FISH AND FISHERIES

M.G.L. ch.130 § 1 Definitions; Rules of Construction contains definitions of “fish” that includes any shellfish and of “shellfish” which includes clams, mussels, oysters, quahaugs, razor clams, scallops, sea clams, sea quahaugs, and sea scallops.
M.G.L. ch.130 § 17 Powers of Director; (10)”….adopt, amend, or repeal all rules and regulations, with the approval of the Governor, necessary for the maintenance, preservation and protection of all marine fisheries resources between the mean high water mark of the commonwealth and a straight line extension of the lateral boundaries of the commonwealth drawn seaward to a distance of 200 miles or to a point where the water depth reaches 100 fathom, whichever is greatest”.
M.G.L. ch.130 § 17A Management of Marine Fisheries; the DMF Director shall adopt, amend, or repeal rules or regulations, subject to approval of the commissioner, which govern the activities, specifically, under (5) the opening and closing of areas within the coastal waters to the taking of any and all types of fish; provided that no area shall be so opened or closed without the consent of the selectmen of the town, or the mayor and council of the city affected thereby.
M.G.L. ch. 130 § 20 Increase in supply of shellfish; co-operation with coastal cities and towns; treatment or purification of shellfish; The director, in the operation of any plant for the treatment or purification or propagation of shellfish, is hereby authorized and directed to investigate and study methods for the treatment or purification of shellfish taken from areas determined under section seventy-four to be contaminated. The director, in the course of such investigation, shall confer with the state department of public health and may expend for expert, clerical and other services and expenses such sums as may be appropriated therefor. The director shall, before exercising the authority to assist and co-operate as provided in this section, receive the advice of the biologist of the division and a written opinion from him thereon.
The director, acting on behalf of the commonwealth and with the approval of the governor and council, may enter into contracts or agreements with agencies of the federal government or any private institute or corporation for carrying out research and laboratory work necessary for purposes of the treatment or purification of shellfish and the propagation of shellfish in the coastal areas of the commonwealth, and may expend such sums as may be appropriated for the purpose.
M.G.L. ch.130 § 20A Propagation of shellfish; co-operation with coastal cities and towns; The director shall assist and cooperate with coastal cities and towns for the purpose of establishing and maintaining a program of self-help to said cities and towns for the cultivation, propagation and protection of shellfish.
M.G.L. ch.130 § 52 Taking of Eels, Shellfish and Sea Worms; Areas in Which Commercial Taking Prohibited; There are fifty-nine (59) coastal communities with municipal shellfish programs. This statute gives municipalities local control over the management of shellfisheries in all waters within their municipal boundaries that are classified as approved. Authority over waters classified as other than approved may be delegated under a management plan developed and approved by the Director of the Division of Marine Fisheries.
“Nothing in this section shall be construed to authorize the aldermen, city council or selectmen to exercise any authority hereunder in areas declared under section seventy-four (Determination of contaminated areas) or under corresponding provisions of earlier laws to be contaminated unless

such action is in accordance with a management plan developed by cities and towns with the assistance and approval of the director."

No city or town shall require a person to be licensed to take shellfish who is accompanying or operating a boat for a person so licensed and who is not otherwise actively engaged in or assisting in such fishing.

M.G.L.ch.130 §57 Shellfish aquaculture licenses: The city council or mayor of any city, or the selectmen of any town, may upon written application, accompanied by plans sufficient to show the intended project and project area to be licensed, and after public notice and hearing pursuant to section sixty, grant to any person a shellfish aquaculture license. Said license shall authorize said licensee in such city or town at all times of the year, in, upon, or from a specific portion of coastal waters of the commonwealth, of tidal flats or land under coastal waters: (1) to plant and grow shellfish, bottom/off bottom culture; (2) to place shellfish in or under protective devices affixed directly to the tidal flats or land under coastal waters, such as boxes, trays, pens, bags, or nets; (3) to harvest and take legal shellfish; (4) to plant cultch for the purpose of catching shellfish seed; and (5) to grow shellfish by means of racks, rafts or floats. After receipt of a written application by the city council or selectmen, and after the notice and public hearing requirements of this section are satisfied and the licensing authority approves the application, the director shall, after inspection of the intended project area, certify that issuance of a shellfish aquaculture license and operation thereunder will cause no substantial adverse effect on the shellfish or other natural resources of the city or town. Upon such certification by the director, the city council or selectmen may issue the license, provided, however, that no license shall be issued for any areas then or within two years prior thereto, closed for municipal cultivation under the provisions of section fifty-four. Failure of the director to so certify shall be deemed a denial of the shellfish aquaculture license. The director's certification or refusal to certify shall be reviewable in accordance with section fourteen of chapter thirty A. etc.

M.G.L.ch.130 §65 Annual report of shellfish planted, produced and marketed; estimate of growing shellfish; forfeiture for deficiency; Every licensee or transferee of a license referred to in section fifty-seven shall submit on oath on or before February 28 in each year to the director and to the city council or selectmen of the city or town wherein the licensed area is situated a report of the total number of each kind of shellfish planted, produced or marketed during the preceding year upon or from such licensed area, and an estimate of the total number of each kind of shellfish at the time of such report planted or growing thereon. The city council or selectmen may specify a reasonable yearly market value to be produced by each shellfish project licensed pursuant to section fifty-seven. Failure of the licensed shellfish project to meet such a value for any three consecutive years thereafter may result in a forfeit of the shellfish aquaculture license and licensed area.

M.G.L.ch.130 §68 Digging, taking or carrying away shellfish from licensed waters, flats or creeks at night; No person shall dig, take or carry away any shellfish or shells between one half hour after sunset and one half hour before sunrise, by any method whatever, from any waters, flats or creeks as to which a license under section fifty-seven or corresponding provisions of earlier laws is outstanding. A licensee or transferee of such a license violating this section shall, in addition to all other penalties provided, forfeit his license and the shellfish remaining on the licensed premises. No person shall, without the consent of the licensee or transferee, dig or take any shellfish or shells from any waters, flats or creeks described in a license granted under section 57 or any corresponding provision of earlier law, during the continuance of the license or of a renewal thereof.

M.G.L. ch.130 §69 Seed quahaugs, clams or oysters; taking or possession; Whoever takes or has in his possession quahaugs or soft shelled clams or oysters smaller than the minimum size established by the director through regulations, hereinafter referred to as seed quahaugs, seed clams and seed oysters, to the amount of more than five percent of any batch, shall be punished in accordance with section two; provided, however, that it shall not be unlawful to take seed quahaugs, seed clams or seed oysters or have the same in possession under authority of a permit therefor, which the director is hereby authorized to grant, for a replanting in waters or flats within the commonwealth.

M.G.L. ch.130 § 74 Determination of contaminated areas; notice of results; The division of marine fisheries shall examine from time to time as conditions may require, or upon request of the commissioner of public health, the mayor or city manager of a city, or the selectmen or town manager of a town, the coastal waters and flats of the commonwealth and samples of shellfish therein or thereon in order to determine what areas thereof are so contaminated that shellfish obtained therefrom are unfit for food and dangerous to the public health. The division of marine fisheries shall forward the results of all tests as directed by the commissioner of public health. If, after such examination, either the department of public health or the division of marine fisheries determines that such contamination exists, it shall, by written order, promulgate definite bounds of the area or areas so determined to be contaminated, and may specify the period of time during which such determination shall be in effect. Before such determination shall be in effect, such department or division making the determination shall:

(1) Publish the results of its determination thereof in a newspaper published in each city and town in which or adjacent to which any contaminated area is situated.

(2) File in the office of the clerk of every such city or town the results of the determination.

(3) Cause to be posted at points on or near every such area a description thereof, specifying said bounds and a statement that such an area is contaminated.

(4) If the department of public health makes the determination, notify the directors of the division of marine fisheries and the division of law enforcement of its determination by filing with them properly authenticated copies, certified by the secretary of state, of its determination, publication, filing and posting.

(5) If the division of marine fisheries makes the determination, notify the director of the division of law enforcement of its determination by filing with him properly authenticated copies, certified by the secretary of state, of its determination, publication, filing and posting.

Whenever, as a result of a subsequent examination of an area or areas determined by the division of marine fisheries or the department of public health to be contaminated, such division or said department, as the case may be, determines that the shellfish in such area or areas are safe to use as food, notice of such determination shall be published immediately, and provided to the directors of the division of marine fisheries and the division of law enforcement, in the case of a determination by the department of public health, and to the director of the division of law enforcement in the case of a determination by the division of marine fisheries; provided, however, that if the department of public health or the division of marine fisheries has specified a period of

time during which the determination of pollution shall be in effect, such publication and notice shall not be required if such period has expired. The record of any examination hereunder and the bacteriological counts made therein shall be subject to inspection upon request.

Personnel at the department of public health and the division of marine fisheries in the performance of their duties under this section, may enter upon and pass through or over private lands or property whether or not covered by water.

The presentation in evidence by any officer of the commonwealth empowered to enforce this chapter of a document attested to by the commissioner of the department of public health or the director of the division of marine fisheries or either of their designees to the effect that the provisions of this section have been complied with shall be prima facie evidence that an effective determination has been made.

The department of public health and the division of marine fisheries, acting jointly, after consultation with the department of environmental protection, can promulgate rules and regulations establishing standards and criteria for the classification of all shellfish growing areas within the commonwealth. Such standards and criteria shall conform at a minimum to those established by the national shellfish sanitation program.
This section shall not apply to scallops or conch unless scallops or conch are specifically included in such determination.

M.G.L. ch.130 §74A Emergency designation of contaminated shellfish areas; enforcement; notice to local authorities: Both the department of public health and the division of marine fisheries shall have the authority immediately to designate shellfish areas as contaminated and that shellfish obtained therefrom are unfit for food and dangerous to the public health, in the event of an emergency as determined by either the department of public health or the division of marine fisheries. Such designation shall be reported to the division of law enforcement, and, in the case of a determination by the department of public health, to the division of marine fisheries, who shall take the necessary action to prevent the taking of shellfish from such area for human consumption and so notify local authorities in each instance. Such determination shall be in effect until subsequent examination, initiated not more than thirty days after the emergency has been determined, shows the shellfish from such area to be safe for human consumption and the said department or division which designated the emergency declares it to be over. In the event that the department of public health determines that there is an emergency, the commissioner of public health shall have the power to direct the activities of all employees of the division of marine fisheries who are regularly engaged in monitoring the condition of shellfish during that emergency.
This section shall not apply to scallops or conch unless scallops or conch are specifically included in such determination.

M.G.L. ch.130 §75 Shellfish from contaminated areas, permits, purification; shellfish conservation. Allows DMF to issue permits and set permit conditions for depuration and relaying using methods approved in writing by DPH, and bait harvest from contaminated areas.

M.G.L. ch.130 §76 Construction and operation of shellfish purification plants; powers of commissioner

M.G.L. ch.130 §80 Commercial permits and certificates; issuance; transfers; wholesale dealer permit; regulated marine fishery permit; rules and regulations; cancellation; revocation; penalties

M.G.L. ch.130 §83 Permit fees; types of permits

M.G.L. ch.130 § 98 Shellfish constables; appointment; powers and duties; notice of appointment: Each city and town bordering on coastal waters shall appoint a person or persons, qualified by training and experience in the field of shellfishery management, as shellfish constables or deputy shellfish constables. A person having successfully completed the shellfish wardens training course shall be considered qualified and eligible for appointment as a shellfish constable or deputy shellfish constable. Municipal shellfish constables and deputy constable's appointments are for three (3) year terms, subject to reappointment. Municipal shellfish constables and deputy shellfish constables shall enforce all statutes, ordinances, by-laws, rules, and regulations relative to shellfish in their municipality. Shellfish constables and deputy constables may request any person, for cause, to display for inspection, all shellfish in his/her possession, and may arrest without a warrant any person refusing to comply with the request. A municipality appointing a shellfish constable or deputy constable must notify the DMF and the OLE [Office of Law Enforcement] regarding the appointment. The shellfish constables and deputy constables notify the OLE of illegal activities, assist with marking classification boundary lines, posting closed area signs, and enter into MOA [Memorandum of Agreement] with the DMF for conditional area management. The municipal wardens regularly interact with the OLE EPOs [Environmental Police Officer] by way of field support and observational information. The municipal shellfish constables and deputy constables are responsible under conditional area management plans to open/close conditional areas. The municipal shellfish constables and deputy constables patrol activities do not reduce the patrol efforts required of the OLE.
M.G.L. ch. 130 § 75 Shellfish from contaminated areas, permits, purification; shellfish conservation; Allows DMF to issue permits and set permit conditions for depuration and relaying using methods approved in writing by DPH, and bait harvest from contaminated areas.

ii. Regulation(s)

Code of Massachusetts Regulations (CMR):

105 CMR 300.000: REPORTABLE DISEASES, SURVEILLANCE, AND ISOLATION AND QUARANTINE REQUIREMENTS
105 CMR 400.000: STATE SANITARY CODE CHAPTER I: GENERAL ADMINISTRATIVE PROCEDURES
105 CMR 500.000: GOOD MANUFACTURING PRACTICES FOR FOOD

The following is the web link to the CMR Title 322: https://www.mass.gov/law-library/322-cmr

322 CMR 6.00: Regulation of Catches contains the requirements for **6.08**: Surf Clam and Ocean Quahog Fisheries, **6.11** Bay Scallops Harvest Criteria, **6.20**: Quahogs, Soft Shelled Clams and Oysters, including other sections which all deal with fishery and/or aquaculture management and not public health.
322 CMR 6.20 Quahogs, Soft Shelled Clams and Oysters
322 CMR 6.38: Shellfish Landing Restrictions Necessitated by Marine Biotoxins; allows the Director of DMF to restrict the taking or landing of shellfish from areas determined to contain levels of toxic phytoplankton that may place the public health at risk by vessels registered under laws of the Commonwealth, including from waters within the Exclusive Economic Zone.
322 CMR 7.00 Permits

322 CMR 7.01 defines shellfish as clams, conchs, limpets, mussels, oysters, periwinkles, quahogs, razor clams, bay scallops, sea scallops, surf clams, ocean quahogs and winkles. This section also deals with permitting including depuration, relaying and contaminated bait. 322 CMR 7.01 (2.) Commercial Fisherman Permits. In order to harvest, possess or land fish, shellfish or bait for commercial purposes, the following permits are required for the following fishing activities:
(g) Shellfish and Seaworms. Authorizes only the named individual to harvest, possess and land shellfish and seaworms for commercial purposes, and may be endorsed for the shucking of bay scallops.
(h) Individual. Authorizes only the named individual to harvest, possess and land fish for commercial purposes. Said permit may be endorsed upon request of the applicant for the harvest, possession and landing of shellfish and seaworms for commercial purposes.
(i) Shellfish/Rod and Reel. Authorizes the harvest, possession and landing of shellfish for commercial purposes and/or the harvest, possession or landing of fish by means of a rod and reel for commercial purposes subject to 322 CMR 7.01(10).
(k) Shellfish Transaction Card. Authorizes only the named individual holding a commercial fishermen permit endorsed for shellfish and seaworms to sell shellfish and seaworms and shall be used in conjunction with either a Massachusetts driver's license or a Registry of Motor Vehicles identification card.
322 CMR 7.01 (4.) Special Permits allows the Director of DMF to issue special permits for the following activities under (1.) Open Access Regulated Fishery Permit Endorsements, specifically:
(a.) (1.) (b.) Bay Scallop Shucking. For a named individual and/or vessel to shuck bay scallops at-sea for commercial or non-commercial purposes.
(a) (1.) (d.) Contaminated Surf Clam. For a named individual and/or vessel to operate a surf clam dredge in shellfish growing area designated by the Division as "PROHIBITED" and to harvest, possess or land surf clams taken from a shellfish growing area designated by the Division "PROHIBITED" for the purpose of being kept or sold as bait.
(4)(c) Special Project. Authorizes only the names individual to engage in a specified marine fishery project including, but not limited to, aquaculture or mariculture; scientific, environmental and biological collection and study, assessment or experimentation; collection and possession for education purposes; shellfish relay; and shellfish propagation.
h. Sea Scallop Diving. For a named individual to commercially fish for sea scallops by hand within the waters under the jurisdiction of the Commonwealth, or to harvest, possess or land sea scallops for commercial purposes that were taken by hand in the Commonwealth.
i. Sea Scallop Shucking. For a named individual and/or vessel to shuck sea scallops at-sea for commercial or non-commercial purposes.

322 CMR 7.01 (2.) Limited Entry Regulated Fishery Permit Endorsements
(i.) Ocean Quahog and Surf Clam Dredge. For a named individual and/or a vessel to operate an ocean quahog and/or surf clam dredge or to commercially fish for, harvest, possess or land ocean quahogs or surf clams taken by ocean quahog and/or surf clam dredge gear from the waters under the jurisdiction of the Commonwealth.
j. Quahog Dredge. For a named individual and/or vessel to operate a bay quahog dredge or to commercially fish for, harvest, possess or land bay quahogs taken by bay quahog dredge gear from the waters under the jurisdiction of the Commonwealth seaward of the outer jurisdiction of coastal cities and towns to regulate shellfish pursuant to M.G.L. c.130, § 52, as appearing on official maps of the Commonwealth prepared pursuant to M.G.L. c. 1 § 3.

322 CMR 7.02: Master and Subordinate Digger Permits Master Digger section contains the requirements for persons authorized by the DMF to engage in the harvest, possession and transportation of moderately contaminated shellfish from areas classified 'restricted' and suitable for depuration at the plant operated by the DMF located at Plum Island, Newburyport, Massachusetts. Subordinate digger means any person authorized by the DMF to harvest and possess moderately contaminated shellfish for sale only to a master digger. Master and subordinate digger permit applicants must submit a signed statement that the applicant has read, is familiar with, and agrees to comply with 322 CMR 7.02 and 10.00: Management of Moderately Contaminated Shellfish, M.G.L. c. 130, §§ 74A, 75 and 80 and any other conditions or restrictions applicable to the permit issued by the DMF.

322 CMR 10.00: Management of Moderately Contaminated Shellfish. Regulates the permitting, harvest, transport, depuration and tagging of moderately contaminated shellfish from restricted and conditionally restricted areas.

322 CMR 14.00: REGULATION OF AQUACULTURE PRODUCTS, 14.03: Sale of Aquaculture Reared Shellfish That Do Not Conform to Wild Caught Minimum Sizes Additional requirements for aquaculture operations are published in
322 CMR 15.00: Management of Marine Aquaculture.

322 CMR 16.00: SHELLFISH HARVEST AND HANDLING

322 CMR 16.01 Background and Purpose
322 CMR 16.02 General Definitions
322 CMR 16.03 Shellfish Growing Area Classification
322 CMR 16.04 The Sanitary Harvest, Handling, and Transportation of Market Bound Shellfish: prohibits the harvest and possession of shellfish by commercial harvesters and wholesale dealers from any area not open to commercial harvesting by DMF or the municipalities. This includes all areas closed due to contamination.
322 CMR 16.05 deals with **Tagging of Shellfish** consistent with the NSSP
322 CMR 16.07 *Vibrio* Management Plan for Harvest and Handling of Oysters establishes the requirements and performance standards for harvesters and dealers associated with the management of *Vibrio parahaemolyticus.*
322 CMR 16.08 Municipal Contaminated Shellfish Relay and Transplant set forth definitions, procedures, and requirements applicable to the harvest, relay and transplant of contaminated shellfish by municipalities from shellfish growing areas classified as restricted, conditionally restricted, or conditionally approved in the closed status to shellfish growing areas approved by the municipal shellfish department and classified as approved or conditionally approved in the open status for natural purification and propagation of shellfish. The provisions of 322 CMR 16.08 are intended to ensure that contaminated shellfish relay and transplant activities conducted
by municipalities comply with the NSSP thereby minimizing the risk of food borne illness to consumers, preventing the diversion of contaminated shellfish into commerce or for personal consumption.
322 CMR 16.09 Possession of Shellfish from Areas Closed to Commercial Harvesting
322 CMR 16.11 Authority to Suspend Permits for Violations of 322 CMR 16.00 gives the Director of DMF authority to suspend permits without a hearing of any harvester or wholesale dealer that violates the provisions of 322 CMR 16.00.

Executive Office of Energy and Environmental Affairs, DEP, Massachusetts Surface Water Quality Standards, **314 CMR 4.06** (1)(d)(5) Shellfishing - these waters are subject to more stringent regulation in accordance with the rules and regulations of the MA DMF pursuant to M.G.L. c. 130, § 75. These include applicable criteria of the NSSP. Approval for use of areas designated for shellfishing is issued by the DMF. To determine whether a particular water designated for shellfishing also is approved for use, the DMF and/or the appropriate local authority (usually the Shellfish Department) should be contacted.

301 CMR 26.00: Coastal Pollution Remediation Program

323 CMR 2 The Use of Vessels, 2.07 (6) Discharge. The discharge of raw sewage, garbage, rubbish or debris from motorboats on or into the waters of the Commonwealth is prohibited.

The Commonwealth of MA has promulgated Massachusetts General Laws (M.G.L.) and Code of Massachusetts Regulations (CMR) to provide an adequate legal basis for the safety and sanitary control of shellfish. The harvest of shellfish (clams, oysters, and mussels) is subject to the permitting requirements and under the jurisdiction of the local municipalities (cities and towns). Municipal shellfish conservation programs issue commercial shellfish licenses to allow shellfish harvesters to harvest in the shellfish growing areas within their municipal boundary. Municipal shellfish programs may also issue resident and non-resident recreational harvesting licenses for people to harvest shellfish in the shellfish growing areas. The municipal shellfish program may not allow harvesting in an area closed by the MA DMF. The MA DMF has the authority to regulate commercial harvest of surf clams (*Spisula solidissima*), ocean quahogs (*Artica islandica*), and all shellfish taken from contaminated areas. All persons who land and sell shellfish in Massachusetts must possess the following:

- A municipal commercial shellfish permit (M.G.L. ch.130 §52 and municipal regulation), and
- A state commercial fishing permit with a shellfish endorsement from the DMF (M.G.L. ch.130 §80 and 322), and
- A shellfish transaction card issued by the DMF pursuant to 322 CMR 7.01 (2.) (k.).

All persons may only sell shellfish to Massachusetts licensed wholesale dealers with a permit authorizing them to purchase shellfish (M.G.L. ch130 §80). To obtain a shellfish endorsement, applicants must sign a Shellfish Harvesting, Handling, and Transport Affidavit to submit with their commercial fishing permit application. Pursuant to 322 CMR 7.01 (11.) permits expire each year on December 31st.

c. Record Keeping [Chapter I @.01 C.]

The MA DMF and the MA DPH maintain records to demonstrate the effective administration of the statewide shellfish program at their central offices in Gloucester, MA, New Bedford, MA, and Jamaica Plain, MA, respectively. The records are available, either physically or electronically, to any interested person upon request, pursuant to appropriate state and federal law.

d. Shared Responsibilities [Chapter I @.01 D.]

The administration of the MA shellfish sanitation program related to vibrio risk management is a shared responsibility between three (3) state agencies, the municipal shellfish programs, and the local boards of health. Two (2) of the state agencies are within the MA Executive Office of Energy and Environmental Affairs, Division of Marine Fisheries (MA DMF) and Office of Law Enforcement, e.g., MA Environmental Police (MA OLE), and the MA Department of Public Health, Food Protection Program (MA DPH) is the third agency. Pursuant to Chapter I @.01 D., the MA DMF, MA OLE, MA DPH, the municipalities (including the local boards of health), having shared responsibilities for the administration of the statewide shellfish program, must enter a Memorandum of Agreement (MOA) defining each participant's NSSP responsibilities. The FDA cited this as a deficiency and MA will continue under the action plan submitted in response to the Growing Area Classification, Plant Processing and Shipping, and Control of Harvest PEERs. Please refer to section B.3 and B.8. for additional details.

The MA DMF manages the statewide shellfish program in accordance with M.G.L. chap. 130, §§ 74 and 74A, by classifying shellfish growing areas based on the results of a sanitary survey. The municipalities control the regulation and management of both commercial and non-commercial shellfisheries in waters under municipal control, provided such waters are classified by the DMF as approved or conditionally approved in the open status. Municipal programs manage conditionally approved areas under a MA DMF approved CAMP; municipalities open and close the conditionally approved areas based on performance criteria in the CAMP. Municipalities enforce the state's VpCP within their boundaries.

Areas classified restricted or conditionally restricted are subject to MA DMF control unless the DMF has an approved local Shellfish Conservation and Management Plan. Pursuant to M.G.L. chap 130 § 75, municipalities are granted limited shellfisheries management authority when these areas are in the open status, but they cannot change the sanitary status of these areas on their own, the MA DMF is responsible for providing public notification of status changes.

Pursuant to M.G.L. chap. 130 §74, the MA DPH may request that the MA DMF or a municipality examine the coastal waters and flats of the commonwealth and samples of shellfish, in or on the growing area, to determine what areas are so contaminated that shellfish obtained therefrom are unfit for food and dangerous to the public health. The MA DMF shall forward the results of all tests as directed by the MA DPH and if, after such examination, either the DPH or the DMF determines that such contamination exists, it shall, by written order, promulgate definite bounds of the area or areas determined to be contaminated, and may specify the period during which such determination shall be in effect. Before such determination is in effect, the department or division making the determination shall; publish the results in a newspaper in each municipality and adjacent municipality where the contaminated area is, filed in the office of the clerk of every municipality the results of the determination, post signage at points on or near the area a description of the boundaries and a statement that the area is contaminated, and if the DPH makes the determination, notify the DMF and OLE of the determination by providing certified, authenticated copies of the determination, publication, filing, and posting.

The MA DMF, MA DPH, and MA OLE participate in one (1) memorandum of understanding for The Depuration of Shellfish at the Shellfish Purification Plant in Newburyport (December 2017) outlining the responsibilities of each agency.

e. Administrative Procedures [Chapter I @.01 E.]

The MA DPH has sufficient administrative procedures to ensure that all shellfish shipped in interstate commerce originate from certified dealers located within the state. The MA DPH does not have any MOA with other states to allow dealers from MA to purchase shellstock harvested and landed in another state.

The MA DPH has the authority to embargo or condemn contaminated or adulterated shellfish products.

f. Epidemiological Implicated Outbreaks of Shellfish-Related Illness. [Chapter I @.01 F.]

Pursuant to Chapter I @.01 F. (1) and (2), the MA DPH must have a written protocol with the appropriate state agencies responsible for collecting epidemiological information related to reported foodborne illnesses. The MA DPH has a written protocol entitled Foodborne Illness Investigation and Control Reference Manual (February 2019) that outlines the procedures and responsibilities for local boards of health (LBOH) and the MA DPH, including specifics for investigating incidents of shellfish borne disease (Chapter I @.01 F. (2)).

Additionally, the MA DPH Bureau of Infectious Disease and Laboratory Sciences (BIDLS) has an online Guide to Surveillance and Reporting available to assist LBOH with specific surveillance, response, and reporting responsibilities for infectious diseases reportable to the LBOH and the MA DPH. Each disease specific chapter contains general information about the disease, control recommendations and reporting requirements. The Vibriosis guide (attachment 9), section 3 Reporting Responsibilities and Case Investigation, A. Purpose of Surveillance and Reporting has the following related to shellfish:

"• To identify sources of infection of major public health concern (e.g., contaminated shellfish growing areas, improper handling of shellfish that may lead to proliferation of bacteria, contaminated water, or other food), and to stop transmission from such a source.

• To identify cases of vibriosis to prevent further infections."

The guide further describes reporting and follow-up responsibilities pursuant to MA DPH regulation 105 CMR 300.000 that requires vibriosis cases as reportable to the LBOH and that each LBOH must report any confirmed case of vibriosis or suspect case of vibriosis. Cases should be reported to the MA DPH BIDLS, Office of Integrated Surveillance and Informatics Services (ISIS) via MAVEN. MAVEN is an acronym for the Massachusetts Virtual Epidemiologic Network surveillance system. MAVEN is a web-based disease surveillance and case management system enabling the LBOH and MA DPH divisions, bureaus, and laboratories to capture and transfer public health, laboratory, and clinical data over the internet in real-time. Laboratories performing examinations on any specimens derived from MA residents that yield evidence of *Vibrio sp*. shall report such evidence of infection directly to the MA DPH. Additionally, all laboratories performing examinations on any specimens derived from MA residents are required to submit all

Vibrio sp. isolates directly to the MA State Public Health Laboratory for further examination.

105 CMR 300.100 Diseases Reportable to LBOH requires cases or suspect cases of the diseases listed in the regulation e.g., toxin illnesses, hepatitis, norovirus, vibriosis, etc. be reported by household members, physicians, other health care providers, and other officials designated by the MA DPH, by telephone, in writing, by facsimile or other electronic means (e.g., MAVEN), as deemed acceptable by the MA DPH, including transmission from electronic health records, immediately, but in no case more than 24 hours after diagnosis or identification, to the LBOH in the community where the case is diagnosed or suspect case is identified. Diseases ascertained through laboratory testing and reported to the MA DPH may serve as reporting in lieu of direct reporting to LBOH.

105 CMR 300.110 Case Reports by Local Boards of Health require each LBOH to report to the MA DPH the occurrence or suspected occurrence of any disease reported to them. When available, the case's full demographic, clinical, and epidemiologic information must be included for each report. Each LBOH shall utilize MAVEN and each case shall be reported immediately, but no later than 24 hours after receipt by the LBOH. If the MA DPH is notified directly, it shall notify the LBOH within 24 hours.

According to the Vibriosis guide, LBOH are to monitor their "Online LBOH Notification for Immediate Disease" workflow in MAVEN for any new cases of vibriosis during the months of May – October. An MDPH Epi-of- the-Day (EOD) will review all new cases and request immediate follow up for *V. parahaemolyticus* events. The LBOH is responsible for the case investigation. Once a new event appears in the workflow, the LBOH must open the event and acknowledge they have accepted the case by selecting 'yes' which will auto populate the day of acknowledgement. The event will then be moved into the LBOH staff members pending workflow where they will then add their name, agency, and contact information. The investigator then fills out MAVEN information screens related to case demographics, clinical information, and risk exposure.

The guide instructs the LBOH case investigator(s) to obtain as many details as possible, e.g., date and time of purchase, amount consumed, where seafood/shellfish originated for all seafood/shellfish consumption cases associated with vibriosis. The information must be entered into MAVEN. The actual traceback section in MAVEN is not completed by the LBOH. The traceback section in MAVEN is completed by the MA DPH FPP after the LBOH case investigator marks the case report form completed. If the LBOH is not successful in communicating with the case and cannot complete the investigation, then the investigator selects 'no' with a reason (e.g., case can't be contacted, case refuses to give information, etc.) in MAVEN. These cases are reported as 'lost to follow up'.

The MA DPH Foodborne Illness Investigation and Control Reference Manual (February 2019) outlines the disease characterizations, foodborne illness surveillance, investigating foodborne illnesses and outbreaks, epidemiological investigation, and conducting an environmental investigation, etc. The reference manual, the Guide to Surveillance and Reporting, and 105 CMR 300.00 do not specifically outline the procedure to ensure that all shellfish related illnesses are reported to the shellfish authority(ies) (MA DPH/MA DMF) as required by Chapter I @.01 F. (1.); the documents and regulation require reporting to the LBOH which are not the shellfish authorities. The expectation (Chapter II @.01) is when an illness investigation indicates that there is an

epidemiological association between shellfish consumption and the illnesses (or an outbreak), the investigating authority (MA DPH) shall immediately inform the producing authority (MA DMF) of the illnesses, the stage of the investigation, and epidemiological link to consumption of molluscan shellfish. Prompt reporting, even in the initial stages of an investigation, would allow the producing authority (MA DMF) to conduct its investigation (in accordance with Chapter II. @.01 B.) and determine whether harvest area closure, notification, and recall are required. The lag time created by the LBOH investigating illnesses does not allow for prompt reporting since the LBOH must finish their investigation before the MA DPH FPP begins work on the traceback section. Pursuant to Chapter II @.02 A., with all illness investigations being conducted by LBOH, the MA DPH will not be able to determine the number of cases within the specified time frames to determine implicated areas and whether a closure/recall is required. The FDA is documenting this as a new or emerging concern, please refer to section B.5. for additional details.

Pursuant to Chapter I @.01 F. (2), the Vibriosis guide (online Guide to Surveillance and Reporting) contains procedures for investigating incidents of shellfish borne disease; however, other guides e.g. norovirus, does not have procedures for investigating a shellfish case. The FDA is documenting this as a new or emerging concern, please refer to section B.5. For additional details.

g. Outbreaks of Shellfish-Related Illness [Chapter II @.01]

There were no outbreaks related to shellfish in the state of MA since the 2020-2021 program element evaluation. Therefore, the FDA cannot evaluate conformance with the NSSP MO Chapter II@.01 A.-G requirements since there has not been an outbreak.

The MA DPH in conjunction with a MA certified dealer (Native Cape Cod Shellfish, MA 8821 SS, AQ) initiated a recall of shellfish products (blue mussels) because of public health concerns (Diarrhetic Shellfish Poisoning [DSP]) in accordance with Chapter II @.01 H. on July 15, 2022 (See Attachment 4 for the recall notice and section B.1.k for more information). The MA DPH followed Chapter II@.01 H requirements for the recall and is in conformance at the time of writing this report. The FDA is waiting for the final disposition of all recalled shellfish from the retail establishments on Cape Cod, MA, where the implicated product was sold. The FDA will follow up on this during the next evaluation.

No molluscan shellfish product was recalled because of illness outbreak(s) associated with *Vibrio vulnificus* (V.v.), *Vibrio parahaemolyticus* (V.p.), or norovirus since the previous evaluation covering calendar years 2020, 2021, and January 1-July 31, 2022. (Chapter II @.01 I).

h. Shellfish Related Illnesses Associated with Vibrio parahaemolyticus (V.p.) [Chapter II @.02]

Pursuant to NSSP MO Chapter II @.02 A. (1.), the MA DMF made reasonable attempts to ensure compliance with the state VpCP by sending letters of notification to towns associated with confirmed Vp cases. The letters advised the town shellfish control authorities to continue verification of harvester compliance with the MA 2021 and 2022 VpCP and 322 CMR 16.05. The following towns received letters of notification as of the writing of this report for January 1-July 31, 2022:

- Town of South Dennis dated July 15, 2022, for a single case of Vp linked to oysters harvested from Dennis North Coastal (CCB23) on May 22, 2022 and consumed raw on June 1, 2022.
- Town of Wareham dated July 25, 2022, for one (1) case of Vp linked to oysters harvested from Little Harbor/Bourne Cove (BB37) on June 24, 2022 and consumed raw on June 27, 2022.

There were no closures to shellfish growing areas in 2021 through July 2022 in MA due to Vibrio illnesses and there were no product recalls initiated by the MA DMF or MA DPH in 2021-July 2022 due to Vibrio illnesses.

The MA DMF and MA DPH did not exceed the thresholds for illnesses associated with Vp per the NSSP MO Chapter II@.02 A. (2-6) to institute mandatory closures in 2021 through July 2022, therefore, compliance with these requirements were not assessed at the time of writing the PEER in July 2022.

i. Annual Assessment of Vibrio vulnificus and Vibrio parahaemolyticus Illnesses and Shellfish Production [Chapter II @.03]

The MA DPH and MA DMF investigated 33 confirmed *Vp* illnesses involving consumption of raw oysters in 2021 (Table 1). Illness investigations (16) were single-source trace backs to one of several MA shellfish growing areas. The highest number of single-source illnesses were from Katama Bay (V20), with six (6) cases. Three (3) cases were harvested from Buzzards Bay growing areas, five (5) cases were harvested from various Cape Cod Bay growing areas, one (1) case from the Elizabeth Islands and a single case was from a Mount Hope Bay (MHB4) growing area. One (1) of the Buzzards Bay illnesses and the MHB4 illness were associated with recreational self-harvest. Three (3) multi-source illness tracebacks involved oysters from only MA growing areas, nine (9) cases implicated both in-state and out-of-state growing areas and five (5) illnesses involved only out-of-state oysters. Eight (8) additional investigations and trace backs were completed for illnesses associated with raw oyster consumption that were confirmed *Vibrio* genus, but species was not identified. Two (2) involved single-source trace backs to MA growing areas (CCB45 and V20), two (2) implicated multiple in-state growing areas, two (2) involved out-of-state sources (NY, RI and Canada) and two (2) were lost to trace back. See Attachment 1 for more information on the annual assessment.

There were no growing area closures occurred during the 2021 *Vibrio* season.

Table 1. Single-Source and Multi-Source Vp Cases by Year

Year	Vp Illness- MA Single-source	Vp Illness- Multi-sources within MA	Vp Illnesses- Multi-sources (Out-of-state and/or MA sources)
2015	24	3	3
2016	9	3	1
2017[1]	14[2]	2	5
2018[3]	8[2]	10	18
2019	8	4	3
2020	8	4	3
2021	16	3	14

1. Data from 2017 includes all illness reports received by the DMF and DPH for the period January 1-December 31, 2017.
2. Number includes cases where a single growing area in MA was implicated as well as cases where two (2) or more hydrologically linked growing areas in MA were implicated during a trace back which was considered a single source by the DMF and DPH.
3. Data from 2018 includes all illness reports received by the MA DPH and MA DMF for the period January 1-December 31, 2018.

The MA DMF collects monthly and reports the volume of shellfish harvested in the state annually to the Interstate Shellfish Sanitation Conference (ISSC) per NSSP MO Chapter II @.03 B. requirement. The MA DMF reported 2021 landings data by month and species on July 12, 2022 via email to the ISSC.

j. Presence of Human Pathogens in Shellfish Meats [Chapter II @.04]

MA has not determined that human pathogens are present in shellfish meats and therefore has not had to implement Chapter II @.04 A. – C. The MA DPH and MA DMF did follow Chapter II@.05 A. which references Chapter II@.04 D. in the NSSP MO. There was a Diarrhetic Shellfish Poisoning (DSP) bloom event in the Nauset System in Eastham, MA that resulted in a recall of blue mussels in July 2022. Please refer to next section (k.) for details.

k. Presence of Toxic Substances in Shellfish Meats [Chapter II @.05]

The MA DMF implemented a closure to shellfish growing area OC4 (Town Cove, Eastham, and Orleans) on July 9, 2022 due to a *Dinophysis sp.* bloom.

The MA DMF collected shellfish tissue samples on July 11, 2022 and sent them to the FDA's Center for Food Safety and Applied Nutrition (CFSAN) Office of Regulatory Science (ORS), Division of Analytical Chemistry, Methods Development Branch laboratory, which were received and analyzed by the FDA on July 12, 2022. The FDA laboratory tested the shellfish tissues for okadaic acid toxin levels (Diarrhetic Shellfish Poisoning [DSP]). All samples (oysters, blue mussels, quahogs [hard clams]) had detectable levels of DSP-like activity. Oysters from Nauset Harbor/Hemenway were below the 0.16 ppm guidance level (0.085 ppm total DSTs), quahogs (hard clams) from the Town Cove recreational harvest area had 0.16 ppm total DSTs, and mussels from Nauset Harbor/Hemenway were above the guidance level (0.31 ppm total DSTs). The MA DMF subsequently closed shellfish growing areas on July 13, 2022 in the Nauset marsh system (growing areas OC2, OC3, OC4, OC5 and OC6) due to the elevated levels of okadaic acid, the cause of Diarrhetic Shellfish Poisoning (DSP).

Additional shellfish samples collected on August 9, 21, and 28 were processed by FDA's CFSAN laboratory. OC2-6 was reopened to the harvest of all bivalves except blue mussels. These growing areas have an indefinite closure for carnivorous snails. Based on consecutive DSP toxin results below the guidance level and a complete absence of Dinophysis cells in the water, the blue mussel closure was lifted on September 7th. The state of MA meets the requirements of Chapter II @.05.

MA took the necessary corrective actions in accordance with the procedures listed in Chapter II @.04 as of the time of writing this report.

The MA DMF met the requirements of Chapter II @.04 D. (1) by performing surveillance sampling to determine if the growing areas demonstrate the presence of toxic substances in the absence of illnesses. As of the time of writing this report the MA DMF continued to monitor the *Dinophysis sp.* bloom in the Nauset system and was planning to collect additional shellfish samples to be sent out for testing for okadaic acid levels.

The FDA will follow up on the reopening procedure used by the MA DMF for the Nauset system during the next evaluation.

l. Vibrio vulnificus Control Plan [Chapter II @.06]

The Commonwealth of MA is not required to have and implement a *Vibrio vulnificus* control plan. The MA DMF and MA DPH conducted an annual *Vibrio vulnificus* (Vv) risk evaluation as part of the Vp risk evaluation in 2022 (Attachments 1-2). The MA DMF determined that no Vv control plan was needed for shellstock harvested from MA growing areas at this time. The MA DMF complies with the requirements under the NSSP MO Chapter II @.06 A.

m. Vibrio parahaemolyticus Control Plan [Chapter II @.07]

The MA DMF and MA DPH conducted an annual Vibrio parahaemolyticus risk evaluation in 2022, which considered the seven (7) required factors from the NSSP MO Chapter II.@.07 A. (1-7) for oysters and hard clams. The MA DMF and MA DPH determined that no VpCP was needed for hard clams in 2022 (Attachment 2). The MA DMF and MA DPH determined that a VpCP was required for oysters harvested from waters throughout the state and there are more stringent controls in place for growing areas linked to confirmed Vp illnesses in the past (Attachment 1). Please refer to Attachment 3 of this report for information regarding the State's VpCP.

The MA DMF required the commercial harvest of oysters to be in accordance with the MA 2022 VpCP from May 19th – October 19th (Attachment 3). The requirements of the VpCP apply to all market-sized oysters harvested from Massachusetts coastal waters.

Harvesters are required to provide adequate shading of oysters from sunlight immediately after harvest and until the oysters are placed in a shellfish icing container and adequately iced. The 2022 VpCP provides two (2) different time-temperature control guidelines based on the previous Vp illness outbreaks associated with certain growing areas:

- "All market-bound oysters harvested from May 19, 2022 through October 19, 2022 shall be adequately shaded immediately after harvest and remain adequately shaded until placed in a shellfish icing container and adequately iced."

- "All market-bound oysters, with the exception of those described in Section B.7 of this Plan [refer to bullet below], shall be adequately iced within 2 hours of time of harvest or exposure, or prior to leaving the point of landing, whichever occurs first."

- "All market-bound oysters harvested from shellfish growing areas CCB42, CCB43, CCB45, CCB46, CCB47 and V20, between July 1 – September 15,

shall be adequately iced within one (1) hour of time of harvest or exposure, or prior to leaving the point of landing, whichever occurs first."

The VpCP require the adequate icing of oysters after harvest and until they are received by the original dealer. Both VpCPs provide a definition of adequate icing for three (3) scenarios: oysters in mesh bags cooled on ice, loose oysters cooled on ice and oysters held in an ice and water mixture/slurry. For mesh bags containing oysters, the bags "must be completely surrounded by ice, with at least two (2) inches of ice between the bags and the bottom and sides of the [shellfish icing] container, and at least three (3) inches of ice on top". The VpCP allow harvesters to utilize a "single shellfish tag attached to the shellfish icing container provided that all oysters in the shellfish icing container are from a single harvester and a single harvester lot. The tag must be attached at the time of icing and remain attached until received by the original dealer" known as a bulk icing tag.

There is an exception to adequately icing market-bound oysters for harvesters in the 2022 VpCP:

"Exception: Harvesters may be exempted from adequately icing market-bound oysters only if the original dealer takes on the burden of adequate icing (Section C.3) at the landing site and within the time to icing requirements described in Sections B.6 and B.7. The harvester is still required to record the accurate time of icing on the harvester icing tag."

The FDA did not observe any harvesters using this exception during the 2022 in-field evaluation.

The VpCP requires harvesters to tag all containers of market bound oysters with the time of harvest, time of icing, harvest date, harvest area, identification of harvester, type of shellstock and quantity (pieces) and keep a Vp harvest logbook to record oyster harvesting and oyster re-submergence activity. The VpCP provide guidelines for oyster handling and re-submergence for aquaculturists under section B.12.(a-f). The VpCP outlines requirements for original dealers [VpCP Section C. (1-10)], which includes the implementation of a HACCP plan with critical control points at the receiving, cooling, and refrigerated storage steps.

The MA DMF also approves resubmergence plans for oysters that will be resubmerged and harvested during the Vp control season. The plans are specific to each harvester, provide a description of how the activity will be conducted, and requires that resubmergence activities be logged into the harvester's Vp logbook in accordance with 322 CMR 16.07 (4) (a – d). Individual harvester Shellfish Aquaculture Permit conditions also provides a reference to the required controls that need to be in place for oysters that are culled off-site during the Vp control season.

n. Laboratory Element [Chapter III @01 and @02]

The MA DMF laboratories support the Vibrio program. The MA DMF collects oyster shellstock samples and these are analyzed using the most probable number (MPN) to alkaline phosphatase (AP) gene probe method for the enumeration of thermolabile hemolysin gene (tlh) and the thermostable direct hemolysin gene (tdh) as described in the FDA Bacteriological Analysis Manual (BAM). The MA DMF uses the trh AP gene

probe and the MPN-real-time polymerase chain reaction (PCR) method targeting total Vp and both hemolysin genes tdh and trh. The MA DMF partners with the University of New Hampshire to analyze shellstock samples using the MPN-real-time PCR method. Sequencing is done by MDPH laboratory but does not determine strain type (E. Hickey, personal communication, September 24, 2021).

The MA DMF does not currently use Vibrio testing results for reopening areas (C. Petitpas, personal communication, September 24, 2021). If the MA DMF decides to use the Vibrio testing and results for reopening purposes the laboratory must be evaluated by CFSAN Laboratory Evaluation Officer(s)(LEOs), using NSSP approved methods, and the laboratory must conform to the NSSP MO.

o. In-field Compliance Evaluation

The in-field compliance evaluation consisted of the FDA, MA DMF, and MA DPH evaluating harvester, harvester/dealer, and certified dealer practices and recordkeeping to verify compliance with the 2022 MA VpCP.

The FDA, the MA DMF, and the MA DPH visited 12 harvesters, three (3) certified dealers and evaluated two (2) refrigerated buy trucks (at landing) during the FY2022 evaluation.

The FDA, the MA DMF and the MA DPH visited aquaculture sites in multiple growing areas and landing sites to verify compliance with required harvester records and time-temperature requirements of the 2022 MA VpCP. On July 19 and July 20, 2022, the harvesters were observed to be in compliance with the MA VpCP and NSSP MO requirements for market-bound oysters. All oysters were cooled using the ice slurry method, and the oyster temperatures were <45°F at landing within the time permitted in the VpCP.

The FDA, the MA DMF and the MA DPH visited three (3) certified dealers. The dealers' HACCP plans and records were reviewed for compliance with the 2022 MA VpCP and NSSP MO requirements. One (1) dealer visited did not have a HACCP plan updated to meet the MA VpCP for receiving. MA will remain under the existing action plan for this deficiency. The two (2) other dealers visited had HACCP plans that included critical limits at receiving that met the MA VpCP. All dealers visited had adequate records of receiving and tagged product that met the NSSP MO requirement.

The MA DPH continues to work with the certified dealers to update their HACCP plans to include the most recent version of the MA VpCP critical limits.

2. Corrective Actions Taken by State

The MA DPH took corrective action to address the HACCP plan deficiencies on-site during the evaluation of each harvester/dealer and certified dealers.

3. Action Plan(s)

The FDA is not requesting a new action plan because of this evaluation. The MA DPH will continue on the 2018 action plan for the continued deficiency related to the following:

One (1) out of three (3) original shellfish dealers visited had Hazard Analysis Critical Control Point (HACCP) plans that were not in compliance with the 2022 MA *Vibrio parahaemolyticus* (Vp) Control Plan (CP) and did not contain all of the required critical limits for Vp [Chapter X.01 C.(3)].

The MA DPH, MA DMF, and MA OLE will continue to operate under the existing action plan cited in the MA Growing Area Classification, Plant Processing and Shipping, and Control of Harvest PEERs to demonstrate how compliance with the requirement for agencies (the MA DMF, the MA OLE, the MA DPH) having shared responsibilities for the administration of the statewide shellfish program, enter a MOA defining each participant's NSSP responsibilities pursuant to Chapter I @.01 D. Please refer to section B.1.d. for additional details. The FDA will monitor the status of the action plan during the follow up evaluation in FY2023.

4. State Program Accomplishments

The following program accomplishments were provided by the MA DMF and MA DPH via email on September 27, 2022:

- *"MA DMF and DPH convened the Vibrio Working group in April 2022 to assess 2021 Vibrio illnesses and risk, and discuss potential changes for the 2022 VpCP. Minor changes in language for clarification purposes were necessary,*
- *MA DMF with participation from DPH conducted a virtual (May 12th) and two in-person (Eastham on May 5th and Duxbury on May 11th) industry Vp Control Plan training meetings prior to the 2022 Vp Control Season. A separate virtual meeting was held to facilitate a Vp Control Plan question and answer session between MA DMF, DPH and OLE.*
- *Over 100 Vibrio compliance forms have been completed by OLE and local shellfish constables in 2022 thus far to facilitate Vibrio control compliance checks.*
- *MA DMF continues to collect private ice machine documents including sanitation logs and private water source testing results.*
- *During the 2022 Vibrio season, MA DMF is conducting a Vibrio surveillance time-series analysis in four regions of the state: Wellfleet Harbor, Plymouth/Duxbury Bays, Wareham growing areas in Buzzards Bay, and Katama Bay in Edgartown, MA. DMF laboratories are utilizing the trh AP gene probe and the MPN-real-time polymerase chain reaction (PCR) method targeting total Vp and both hemolysin genes tdh and trh. DMF continues to partner with the University of New Hampshire to assess Vibrio strain type in the environmental samples.*
- *DMF was awarded FDA-AFDO Shellfish Equipment Grant funds (Award G-SE-2204-03297) to purchase equipment that would enhance DMF's biotoxin screening and real-time environmental temperature monitoring capabilities.*
- *DMF and DPH presented course content and training at the 2022 Shellfish Constable Training Program in March. This 2-week officer training program is coordinated by DMF and the Massachusetts Shellfish Officers Association (MSOA).*

- *DMF presented a Massachusetts biotoxin update at a session for state regulators at the 2022 Gulf of Maine HAB Science Symposium.*

Two Food Protection Program Inspectors, Jessica Ferreira and Kevin Bernardo, were successfully standardized as State Standardized Inspectors during summer 2022. Both are currently conducting NSSP shellfish facility inspections and are assisting with Vibrio illness investigations. Additionally, in October 2022, the FDA Regional Specialist will provide field training for both inspectors in response to DPH's request for Technical Assistance and/or Training, which was included in its response to the FY2022 Plant Processing and Shipping Element PEER."

5. New or Emerging Concerns

The following new or emerging issues associated with *Vibrio* were identified during the current evaluation:

No.	New or Emerging Concerns
1.	The MA DPH does not have a protocol that outlines the procedure to ensure that all shellfish related illnesses are reported to the shellfish authority(ies) (MA DPH/MA DMF) as required by Chapter I @.01 F. (1.); the documents and regulation require reporting to the LBOH which are not the shellfish authorities.
2.	Pursuant to Chapter I @.01 F. (2), the Vibriosis guide (online Guide to Surveillance and Reporting) contains procedures for investigating incidents of shellfish borne disease; however, other guides e.g. norovirus, do not have procedures for investigating a shellfish case.

6. Technical Assistance and/or Training Requested by the State

The following technical assistance and/or training was requested by the state via email on September 27, 2022:

"DMF has an ongoing need for staff training in FD242 and FD342. MA DMF coordinated with Dr. Jonathon Deeds of the FDA CFSAN laboratory for toxin testing associated with the DSP closure in the Nauset System. DMF communicated to Dr. Deeds that we would be procuring Abraxis biotoxin screening kits and associated equipment with our AFDO Shellfish Equipment Grant award (G-SE-2204-03297). Dr. Deeds graciously offered to provide training, specifically in the use of the PP2A kits for okadaic acid. DMF intends accept Dr. Deeds' offer for training and coordinate to identify a mutually convenient time to schedule the training."

7. Summary of the State's Response to FDA Evaluation

The following state' response to the FDA evaluation was provided state via email on September 27, 2022:

"DMF continues to identify harvesters who are using private ice machines. Aquaculture site inspections by DMF staff and Vibrio compliance checks by MA OLE and local shellfish constables indicate a high level of compliance with the Vibrio harvest and handling control measures required by the MA VpCP. MA continues to develop the

necessary MOAs between state and municipal partners responsible for Shellfish program management."

8. Conclusion

The FDA's FY2022 Risk Assessment and Risk Management program element evaluation did not identify any new program deficiencies. The MA DPH will continue to operate under the existing action plan to address dealers not having the correct critical limits at the receiving critical control point in their HACCP plans. The MA DPH, MA DPH and MA OLE will continue to operate on the existing action plan cited in the Growing Area Classification, Plant Processing and Shipping, and Control of Harvest PEERs for entering an MOA defining each agencies' responsibilities for implementing the NSSP.

The FDA identified two (2) new or emerging concerns and made three (3) recommendations. The FDA will conduct a follow up evaluation in FY2023.

9. FDA Recommendations

The FDA makes the following recommendations as a result of the current evaluation:

No.	Recommendations
1.	The FDA recommends that the MA DPH continue to conduct field and document review inspections at the beginning of the *Vp*CP timeframe to ensure that firms are in compliance with critical limits and corrective actions in their HACCP plans and that receiving records, invoices/documentation and tagging are in compliance with the *Vp*CP.
2.	The FDA recommends that the MA DMF and/or the MA DPH continue to monitor ice being used by harvesters that is manufactured from their private residences in order to check compliance with the requirements of the NSSP MO Chapter VIII.02 H. The FDA recommends that the MA DMF and/or MA DPH conduct an in-field inspection of the ice machines in order to confirm harvesters are using the ice machines per the manufacturer's specifications and for sanitary conditions.
3.	The FDA recommends that the MA DPH and/or MA DMF continue to check transportation vehicles at landing sites during the Vibrio control months to make sure the conveyances are prechilled at or below 45°F prior to loading shellstock.

10. Acknowledgements

The FDA wishes to thank Ms. Christian Petitpas (MA DMF), Mr. Gabe Lundgren (MA DMF), Mr. Steven Rice (MA DPH), Mr. Kevin Bernardo (MA DPH), and Mr. Eric Hickey (MA DPH) for their help with coordinating and conducting the field work and for providing the information used to write this report.

11. Attachment(s)

Attachment 1. 2022 MA Vibrio Risk Assessment, Oysters (19 pages)
Attachment 2. 2022 MA Vibrio Risk Assessment, Hard Clams (10 pages)
Attachment 3. 2022 MA Vibrio Control Plan (9 pages)

Attachment 4. MA DPH Recall Notice, DSP (1 page)