

Notice of Agency Rule-making Proposal

AGENCY: 13-188-Department of Marine Resources

CHAPTER NUMBER AND TITLE: Chapter 94 Sanitary Control of Molluscan Shellfish

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

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

BRIEF SUMMARY: This proposal would amend Chapter 94 to reference the most current version of the National Shellfish Sanitation Program Model Ordinance.

Date, time and location of PUBLIC HEARING (*if any*): None.

COMMENT DEADLINE: March 21, 2025

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

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

STATUTORY AUTHORITY FOR THIS RULE: 12 MRS 6171-A

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

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* *Check one of the following two boxes.*

X The summary provided above is for publication in both the newspaper and website notices.

The summary provided above is for the newspaper notice only. Title 5 §8053, sub-§5 & sub-§7, ¶D. A more detailed summary is attached for inclusion in the rule-making notice posted on the Secretary of State’s website. Title 5 §8053, sub-§3, ¶D & sub-§6.

DEPARTMENT OF MARINE RESOURCES

Chapter 94: SANITARY CONTROL OF MOLLUSCAN SHELLFISH

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94.01 Purpose and Scope

The purpose of this chapter is to provide uniform sanitary standards based upon the National Shellfish Sanitation Program Model Ordinance titled “Guide for the Control of Molluscan Shellfish”, which was developed through a Memorandum of Understanding between the U.S. Food and Drug Administration and the Interstate Shellfish Sanitation Conference.

94.02 Definitions

In addition to definitions contained in the “Definitions” section of the Model Ordinance, the following words and terms, when used in this chapter, have the following meaning.

- A. **Buying station.** A vehicle that is leased, owned or rented by the certified dealer and which is used to transport shellstock purchased at a location other than the dealer’s permanent facility.
- B. **Model Ordinance.** The document entitled “National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish”, ~~2019~~ 2023 Revision, Sections I and II, published by the U.S. Food and Drug Administration.

94.03 Adoption by Reference

- A. **Model Ordinance.** The Model Ordinance is hereby incorporated by reference and made part of this rule as if set out in full and all provisions thereof are adopted. The Model Ordinance is available from the Commissioner’s Office at the Department of Marine Resources, 32 Blossom Lane, Augusta, Maine, and online at: <http://www.issc.org/nssp-guide>.
- B. **Authority.** The Maine Department of Marine Resources (DMR) or those entities with which DMR has entered into a Memorandum of Understanding, is the Authority responsible for the implementation and enforcement of the Model Ordinance in Maine.
- C. **Control.** Where there is inconsistency between Chapter 94 and the Model Ordinance, these rules control. Where these rules are silent, the Model Ordinance controls.
- D. **Compliance.** Persons engaged in taking, buying, selling, possessing, processing, depuration, wet storage, and transportation of shellfish shall comply with the provisions of the Model Ordinance.

Exceptions: These requirements do not apply to persons who conduct activities limited to:

1. Personal use as defined by 12 MRS §6001
2. Transporting shellfish as a common carrier as defined by 12 MRS §6001

3. Buying, selling, transporting, shipping or serving shellstock or shucked shellfish purchased from a dealer in the retail trade

94.04 Shellstock Time to Temperature Controls

Harvesters shall comply with the Model Ordinance requirements for time to temperature controls. From May 1 to September 30th, harvesters must comply with Level 3 requirements. From October 1 to April 30, harvesters must comply with Level 2 requirements.

94.05 Prohibited Acts – Harvesters

- A. It is unlawful for any person other than the certified dealer to be in possession of unused certified dealer tags.
- B. It is unlawful to harvest, possess or sell shellstock from areas that are closed due to marine biotoxins pursuant to Chapter 96 and bacterial pollution pursuant to Chapter 95, and in those areas that may be closed by the Department.

Exception: Harvest of shellstock from areas closed due to bacterial pollution pursuant to Chapter 95 may be authorized under the issuance of a depuration certificate.

- C. It is unlawful to commingle shellstock, except as authorized by the Department in accordance with the Model Ordinance.
- D. It is unlawful to conduct wet storage activities except that certified dealers may wet store in accordance with a permit issued by the Department.

94.06 Prohibited Acts – Dealers

- A. It is unlawful for the holder of a shellfish certificate issued pursuant to 12 MRS 6856 to receive, buy, hold, wash, pack, tag or label shellstock in any location other than the permanent facility for which the holder's certificate has been issued.

Exception. Certified dealers holding a buying a station permit may purchase shellfish from licensed harvesters at locations other than the permanent facility for which the holder's certification was issued. The purchase of soft shelled clams at locations other than the permanent facility for which the holder certification was issued requires a buying station permit issued pursuant to §6856 sub-§2-A (D).

- B. It is unlawful to buy or possess shellfish obtained from any source other than shellstock harvested by a licensed harvester from an area classified by the Department as approved or conditionally approved in the open status; or a dealer holding a shellfish certificate.

1. **Exception:** The holder of a depuration certificate or a relay permit from the Department may buy, ship, transfer or transport shellfish from an area classified as restricted or conditionally restricted in accordance with certificate or permit conditions.
 2. **Exception:** The holder of an aquaculture lease or license may buy or possess seed from growing areas in the prohibited classification provided the seed does not exceed the maximum seed size definitions as established in Chapter 2.
- C. It is unlawful to receive, handle, buy, possess, sell, ship or transport shellfish unless each container of shellfish bears a label or tag as required by the Model Ordinance.

Exception: Holders of a bulk tagging permit issued by the Department may bulk tag product.

- D. It is unlawful for any person, other than the depuration certificate holder or an authorized representative, to possess seals issued by the Department for depuration harvesting purposes.

94.07 Shellfish Sanitation Certificates

- A. **Application:** Any person who wants to obtain certification pursuant to §6856 shall:
1. On an annual basis, apply to the Department on forms supplied by the Commissioner and shall provide all information required.
 2. Submit and implement an HACCP plan that is in compliance with the Model Ordinance.
- B. **Authorized Activities:** The shellfish sanitation certificate may authorize its holder to conduct specific activities as follows:
1. **Shucker-Packer Certificate.** The holder of a shucker-packer certificate may grow, harvest, pack, purchase, sell, store, hold, ship, or transport shellfish, whether in shellstock or shucked form. A shucker-packer may shuck shellfish and repack shucked shellfish obtained from other certificate holders.
 2. **Shellstock Shipper Certificate.** The holder of a shellstock shipper certificate may grow, harvest, purchase, store, sell, pack, ship and transport shellstock. A shellstock shipper certificate holder may purchase and sell shucked shellfish obtained from a shucker- packer certificate holder, but shall not shuck shellfish or repack shucked shellfish. A shellstock shipper shall have a facility for proper storage and/or repacking of shellstock, including a means of dry storage of shellfish, such as a walk-in cooler.
 3. **Shellfish Reshipper Certificate.** The holder of a reshipper certificate may sell, ship or transport shucked shellfish or shellstock packed in their original containers, which have been purchased from certified shellfish dealers, to other

certified dealers, retailers or to final consumers. A reshipper shall not shuck, repack, hold or store shucked shellfish or shellstock for sale, shipment or transport. A reshipper may not harvest shellfish or buy from harvesters.

4. **Depuration Certificate**

(a) The holder of a depuration certificate may cleanse shellfish harvested from approved, conditionally approved, restricted or conditionally restricted areas, using a physical plant and processing methods which are approved by the Commissioner and which comply with the requirements set forth in the Model Ordinance.

(b) The holder of a depuration certificate may purchase, receive or harvest shellstock from areas classified as approved, conditionally approved, restricted or conditionally restricted and submit such shellstock to an approved depuration process. The depuration processor may pack, sell, ship or transport the depurated shellstock. A depuration processor shall have a facility, including a means of refrigerated storage of shellfish, such as a walk – in cooler.

C. **Expiration.** Certifications expire April 1st, unless an earlier expiration date is given.

94.08 Harvest of Shellfish for Depuration

A. Each depuration plant certificate holder must submit an application to the Department on an annual basis identifying the names and addresses of all individuals who the certificate holder intends to use as authorized representatives for the depuration plant in depuration harvesting operations. The Commissioner may refuse to authorize any person that he determines to be unsuitable to serve as an authorized representative, taking into account, among other things, whether that person has a record of having committed marine resource law violations.

B. The authorized representative must supervise all members of the depuration harvesting crew and keep accurate records.

C. The authorized representative must record the names of all depuration harvest crewmembers and their current, valid, shellfish harvester's license number, during each day's operation. These records must be available for inspection by Department personnel at all times.

D. The authorized representative must maintain daily records of the quantity of shellfish harvested by each member of the harvest crew and the area where the shellfish were harvested. These records must be available for inspection by Department personnel at all times.

E. The depuration plant authorized representative must notify any municipality with a shellfish management program 48 hours in advance of a scheduled depuration harvest. The notification must include the date, time, and location, as well as the contact information for the authorized representative overseeing the harvest. The notification

must be sent by electronic mail to the town clerk, municipal shellfish warden, chair of the shellfish committee, the Marine Patrol Lieutenant for the Division in which the harvest will occur, and DMRPublicHealthDiv@maine.gov. Any change in schedule will be disseminated through the same process and by other means to provide effective notice as soon as possible.

- F. The depuration plant authorized representative must call the appropriate Maine State Police communications center to notify the local marine patrol officer of the area to be harvested at least 24 hours prior to actual harvesting.
- G. Harvesting in restricted or conditionally restricted areas for depuration purposes may be undertaken only during daylight hours.
- H. The area within which the depuration harvesting will occur must be clearly demarcated with orange flags.
- I. During depuration harvesting activities, all harvest crew diggers must remain in the same area, close enough for immediate supervision of all diggers at all times by the authorized representative.
- J. Each member of a depuration harvesting crew must hold, and possess on his person, a current, valid commercial shellfish license, at all times during depuration harvest activities.

94.09 Transportation and Delivery of Shellfish for Depuration

- A. All shellfish harvested from depuration areas must be placed into an approved vehicle and the vehicle must be sealed immediately. Unless otherwise authorized by the Department, all shellfish harvested must be transported directly to the depuration plant immediately after digging operations are completed.
- B. The vehicles must be sealed with state seals. The authorized representative or the vehicle driver must record the seal number(s) on the daily harvest record.
- C. The authorized representative must maintain harvest records and must record the number of the seal on the vehicle and the time shellfish were placed in the vehicle. The plant manager must also maintain records of shellfish lots, listing each lot by seal number and listing the time the lot arrived at the plant and the time the seal was removed from the vehicle at the plant.
- D. The vehicle used must conform to the requirements set forth in the Model Ordinance.

94.10 State Seals

The Department will issue state seals for depuration harvesting purposes only to a depuration certificate holder. Unused seals must be submitted to the Department of Marine Resources upon cancellation or suspension of a shellfish certificate, or revocation or suspension of a certification to depurate.

94.11 Permits

A. Bulk Tagging of Shellstock Permit

1. A person may not handle, ship, transport, or process shellfish in bulk without a current bulk tagging permit issued by the Department.
2. To obtain a bulk tagging permit, a person must apply on an annual basis to the Department on forms supplied by the Commissioner and must provide all information required.
3. When receiving bulk tagged shellfish, the certified dealer must have a Bulk Tagging Plan approved by the Department.
4. A dealer receiving bulk tagged shellstock must have an intermediate processing plan approved by the Department.
5. Bulk Tagging permits expire April 1st unless an earlier expiration date is given.

B. Wet Storage in Artificial Bodies of Water or in Natural Bodies of Water (Onshore or Offshore) Permits

1. A person may not wet store shellfish without a current wet storage permit issued by the Department.
2. To obtain a wet storage permit, a person must apply to the Department on an annual basis on forms supplied by the Commissioner and must provide all information required. A permit is required for each wet storage site or operation.
3. Prior to commencing construction, all plans for construction or remodeling of onshore wet storage facilities or operations shall be reviewed and authorized by the Department.
4. Wet storage permits expire April 1st unless an earlier expiration date is given.

C. Buying Station Permit

1. A person may not operate a buying station without a current buying station permit issued by the Department.
2. To obtain buying station permit, a person must apply to the Department on an annual basis on forms supplied by the Commissioner and must provide all information required. A permit is required for each buying station operation.
3. **Compliance**

- (a) The vehicle used as a buying station must be leased, owned or rented by the certified dealer and licensed with the appropriate supplemental license for that vehicle in accordance with 12 M.R.S. §6851.
- (b) The vehicle must be properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellstock in compliance with applicable regulations and requirements of the Model Ordinance. Water used for sanitation of the vehicle must be from an approved water source at the certified dealer's permanent facility.
- (c) The vehicle must have a mechanical refrigeration unit, an onboard thermometer and a time/temperature data logger that can be downloaded for review by the Department. The mechanical refrigeration unit must always be operating during the buying station activity and until the vehicle is returned to the permanent facility. The ambient air temperature can exceed the required temperature of 45°F degrees for a period no longer than 2 hours, after which the vehicle air temperature must reach and maintain 45°F.
- (d) The buying station representative must maintain a buying station activity log including, but not limited to, the date and time of purchase, area harvested, names of all harvesters and their shellfish harvester's license number, the date and time of harvest, the quantity of shellstock purchased from each harvester and the temperature inside the conveyance at the start and conclusion of activity at each buying location and upon return to the dealer's permanent facility.
- (e) All shellstock purchased at the buying station must be transported by the certified dealer to the permanent facility for which that holder's certification was issued.
- (f) None of the following activities may occur on or in connection with a buying station: washing of shellstock, packing, tagging, distribution to any person or entity other than the certified dealer's facility.
- (g) The HACCP plan and HACCP records must be kept with the vehicle. A copy of the HACCP plan and records that apply to the buying station/vehicle must be separately identified and kept with the buying station/vehicle.

4. **Supervision**

- (a) The holder of a shellfish certificate shall be responsible for the supervision of all activities associated with the buying station permit.
- (b) Supervision of all buying station activities shall be sufficient to ensure compliance with applicable regulations and requirements of the Model Ordinance.

(c) Lack of supervision and responsibility for the buying station permit, including the non-production of records required to be maintained, shall be grounds for immediate suspension of the permit.

5. Buying station permits expire April 1st unless an earlier expiration date is given.

D. Shellfish Relay Permit

1. A person may not relay shellfish without a permit issued by the Department.

Exception: The relay of seed as described in Chapter 2.90(3)(D)(3) will not require a permit provided the seed is held in an area classified as approved or conditionally approved in the open status for the time specified in the Model Ordinance.

2. To obtain a permit to relay shellfish, a person must apply to the Department on forms supplied by the Commissioner and must provide all information required.

3. Relay permit applications will be reviewed and issued based on the applicant's ability to meet the criteria for safe relay operations.

4. The permit may be conditioned at the discretion of the Department.

94.12 Embargo Procedure for Shellfish

A. In the event that the Commissioner or his agent determines that shellfish should be embargoed, whether for violation of any requirement of the Model Ordinance or for any other reason set forth in 12 M.R.S. §6856(6), the shellfish shall be identified and shall not be sold, shipped, transported, moved or otherwise altered by any person, without the express permission of the Commissioner or his agent.

B. Every single container or lot of shellfish subjected to embargo will be clearly identified. The Commissioner shall retain a copy of all current embargo orders or destruct orders, which includes the amount, species, container or lot description, name and address of the shellfish owner and the reason for embargo. A copy of such orders containing this information shall be given to the owner of the embargoed shellfish.

C. It shall be unlawful to pack shellfish, whether shucked or in shellstock form into mislabeled containers, or to possess mislabeled shellfish. Shellfish shall be considered mislabeled if the label is absent, bears inaccurate information, or is missing information concerning the identity of the packer, shipper, distributor, the area name, the date of harvest, the date of packing or the type and quantity of shellfish in the container.

D. Shellfish that are mislabeled shall be grounds for immediate embargo, condemnation and destruction as being of unsound or unknown quality, and therefore, unsafe.

E. When shellfish samples indicate that those shellfish contain toxin levels exceeding those specified in the Model Ordinance, or the shellfish are suspected of being contaminated or of unsound quality or deleterious to the public health, the Commissioner shall embargo

the contaminated shellfish; as well as any other shellfish which are likely to be contaminated in the same vehicle or facility. The Commissioner shall condemn and order destruction of such shellfish in accordance with the embargo authority granted to the Commissioner of Marine Resources in 12 M.R.S. §6856(6).

94.13 Suspension, Revocation or Nonrenewal of Licenses, Permits or Certification

If the Commissioner determines that an applicant for renewal of a shellfish license, permit, or certificate is not currently in compliance with shellfish sanitation regulations, failed to report, or has failed to comply with shellfish sanitation regulations during the previous license period, the Commissioner may, in addition to any remedy available, including but not limited to suspension or revocation of the license, permit, or certificate in accordance with the procedures established under the marine resources' laws, refuse renewal of the license, permit, or certificate in accordance with the following procedures:

- A. The Commissioner shall advise the applicant for renewal by certified mail, return receipt requested, of the refusal and the grounds for this refusal.
- B. The Commissioner shall advise the applicant for renewal that the applicant has a right to request that an adjudicatory hearing be held before the Department in conformity with 5 M.R.S.A., Chapter 375 subchapter IV. The Commissioner shall advise the applicant that the hearing must be requested in writing and that the written request must be received by the Department no later than 10 days of receipt by the applicant of the notice, by certified mail, of refusal to renew the shellfish license, permit or certificate.
- C. If an adjudicatory hearing is requested, the Commissioner shall schedule a hearing within 10 days of the Department's receipt of the written request for hearing, unless a longer period is mutually agreed to in writing.
- D. Notice of the hearing date, time and location shall be given immediately to the applicant.

Rule-Making Fact Sheet

(5 M.R.S., §8057-A)

AGENCY: Department of Marine Resources

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CHAPTER NUMBER AND RULE: Chapter 94 Sanitary Control of Molluscan Shellfish

STATUTORY AUTHORITY: 12 MRS 6171-A

DATE AND PLACE OF PUBLIC HEARING(S): None.

COMMENT DEADLINE: March 21, 2025

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

This proposal would amend Chapter 94 to reference the most current version of the National Shellfish Sanitation Program Model Ordinance.

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

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

This proposed rule will ensure that Maine is complying with the most recent version of the National Shellfish Sanitation Program Model Ordinance.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B]:

This proposal considered the 2023 National Shellfish Sanitation Program Model Ordinance.

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

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

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

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:
[see §8057-A(2)(A)]

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

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