NOTICE OF AGENCY RULE-MAKING ADOPTION

AGENCY: Department of Marine Resources

CHAPTER NUMBER AND TITLE: Chapter 24 Importation of Live Marine Organisms

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

CONCISE SUMMARY:
This rule amends Chapter 24 to make clarifying changes, including improving and creating definitions as necessary, using consistent terminology, and providing updates throughout the chapter. The rule also allows the Commissioner, in consultation with the Aquatic Animal Health Technical Committee, to issue permits to an approved quarantine facility from facilities that do not otherwise meet the regulation requirements, under certain limited circumstances. Transfer from an approved quarantine facility is permitted only if post-import testing provides satisfactory evidence of freedom from pathogens of regulatory concern for which evidence of freedom was not satisfied at the time of import. The rule allows for consideration of evidence other than direct testing of lots to provide evidence of disease freedom from Ceratomyxosis, Whirling disease, and PKD if importation is only in the form of embryos that have been iodine disinfected before and immediately after import, prior to the time of introduction to the waters of the receiving facility.

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

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

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DEPARTMENT OF MARINE RESOURCES

CHAPTER 24 - IMPORTATION OF LIVE MARINE ORGANISMS

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DEPARTMENT OF MARINE RESOURCES

Chapter 24 - Importation of Live Marine Organisms

24.01 Definitions

In addition to the definitions found in 1 M.R.S.A. §72 and in 12 M.R.S.A. §6001, the following definitions shall apply in interpretation of these importation regulations, Chapter 24:

1. **"Active surveillance"** means laboratory testing which is conducted during the annual hatchery inspection and during spawning as outlined in Chapter 24.21(1)(E), 24.32(4), and 24.34(4).

2. **"Biosecurity"**~~:~~ means precautions taken to minimize the risk of introducing an infectious disease or harmful biological agent into an animal population.

3. **"Blue Book"** means "Bluebook Fish Health Section American Fisheries Society. Suggested Procedures for the Detection and Identification of Certain Finfish and Shellfish Pathogens (Blue Book 2007 Edition)". If a more recent edition is available, the more recent edition will be used.

4. **"Broodstock"** means ~~sexually~~ reproductively mature aquatic animals ~~and/or preselected future broodstock~~ that have been selected or used as part of a defined breeding program. (See each species group for size definitions).

5. **"Chain of custody**" means procedures to account for the integrity of each specimen by tracking its handling and storage from point of specimen collection to final disposition.

6. **"Clinical"** means any visual signs of disease by gross external or internal examination.

7. **"Confidence level"** means the probability of detecting evidence of at least one infected marine organism within the population of marine organisms tested at an assumed prevalence level of the agent.

8. **"Cytopathic effect (CPE)"** means changes in viability, morphology, and/or metabolism of tissue culture cells used in disease surveillance as the result of an infective agent.

~~8~~ 9. **"Finfish"** is defined as live fish, fish ~~eggs~~ embryos, or fish gametes, but does not include aquarium species commonly sold in the pet store trade when raised or held in indoor aquaria with no direct discharge to waters of the State.

~~9~~ 10**."Fish culture facility"** means an establishment where finfish are ~~grown~~ raised ~~for live sale and release into coastal waters of the State of Maine~~ or held live and in which the finfish or the rearing waters will come into contact with waters of the State.

A. **"Marine net-pen facility"** means a stationary, suspended, or floating system of nets or cages in open waters of the State and located within the boundaries of a lease granted by the Maine Department of Marine Resources.

B. **"Land-based facility"** means a facility located above the high tide mark that utilizes artificially created bodies of water for the purposes of rearing, improving, or holding freshwater or marine animals.

~~10~~ 11. **"Gadid"** means fish in the family Gadidae.

12. **"HPR0 ISAV":** Sequence analysis reveals a putative "full-length" nucleotide sequence (105 nucleotides = 35 amino acids) for the highly polymorphic region of gene segment 6 which encodes the stem of the HE protein of Infectious Salmon Anemia Virus (ISAV).

13, **"HPR-deleted ISAV":** Sequence analysis reveals gaps in the nucleotide sequence for the highly polymorphic regions of gene segment 6 which encodes for a shortened stem region (11 to 34 amino acids) of the HE protein of Infectious Salmon Anemia Virus (ISAV).

~~11~~ 14.**"Import"** means to land on, bring into or deposit in any place subject to the jurisdiction of the State of Maine from outside the State of Maine.

A. **"Import for Introduction"** means to introduce marine organisms originating from outside of the State of Maine, directly into coastal waters of the State or into facilities that discharge into waters of the State.

~~12~~ 15. **"Inspection"** means an on-site, statistically-based sampling of all lots of fish ~~on~~ at the facility and resulting laboratory tests and inspection reports conducted by an inspector in accordance with the testing requirements and procedures set forth in these rules.

~~13~~ 16. **"Inspector"** means an accredited, licensed veterinarian or a certified fish health inspector; or, upon approval of the Commissioner, persons recognized by federal or state agencies with responsibility for ~~fish~~ aquatic animal health or ~~fish~~ transfer in the state from which the ~~fish~~ marine organisms ~~or gametes~~ originate. No marine ~~fish~~ organism culture facility owner or employee with direct supervisory authority over a facility may serve as an inspector for their ~~fish culture~~ facility.

A. **"Accredited licensed veterinarian"** means a veterinarian holding a current license to practice veterinary medicine in the state of Maine or elsewhere, and who has also fulfilled the accreditation requirements of United States Department of Agriculture Animal and Plant Health Inspection Service (USDA/APHIS).

B. **"Certified fish health inspector"** means an individual certified by the American Fisheries Society/Fish Health Section (AFS/FHS) as a Fish Health Inspector or Fish Pathologist.

~~14~~ 17. **"Introduce"** means to ~~land on,~~ bring into or deposit in any ~~place subject to the jurisdiction of the State of Maine~~ waters of the State from any restricted areas within the State of Maine.

~~15~~ 18. **"Marine Fish Health Zones"** means the following defined marine geographic areas:

A. Area 1
   (1) Eastern Line - Head of tide on the St. Croix River and International Boundary Line Canada and the U.S. (Maine).
   (2) Western Line - Line from West Quoddy Head Lighthouse extending bearing 40° magnetic to the International Boundary Line Canada and the U.S. (Maine).

B. Area 2
   (1) Eastern Line -Line from West Quoddy Head Lighthouse extending bearing 40° magnetic to the International Boundary Line Canada and the U.S. (Maine).
   (2) Western Line - Line defined by the 68° West Longitude line extending to the limits of the exclusive economic zone (coastal waters).

C. Area 3
   (1) Eastern Line - Line defined by the 68° West Longitude line extending to the limits of the exclusive economic zone (coastal waters).
   (2) Western Line - The State of Maine and State of New Hampshire border.

~~16~~ 19. **"Marine Organism Culture Facility Owner"** means any person, partnership, company or corporation with a proprietary interest in a marine organism culture facility.

~~17 . **"OIE"** means the World Organization for Animal Health ("Office International des épizooties").~~

~~18~~ 20. ~~"New England~~ **"Northeast Fish Health Committee Guidelines"** means the most current available edition of the ~~New England Fish Health Committee Guidelines.~~ Northeast Fish Health Committee (NEFHC) Guidelines for Fish Health Management in Northeastern States.

~~19~~ 21.**"Nonindigenous species"** means an organism belonging to a species that is not native to Maine, ~~that is,~~ and that does not now exist naturally in Maine.

22. **"OIE"** means the World Organization for Animal Health ("Office International des épizooties").

~~20~~ 23. **"Passive surveillance"** means the collection of disease or pathogen data from historical records or diagnostic sampling done during a disease outbreak or a disease investigation.

~~21~~ 24. **"Pathogens of Regulatory Concern"** means infectious agents that ~~have been demonstrated to~~ may cause significant morbidity and/or mortality among marine organism populations in the State of Maine. ~~Pathogens of Regulatory Concern~~ Known pathogens of regulatory concern are classified by the Commissioner into ~~three~~ two (~~3~~ 2) pathogen categories ~~exotic, reportable and non-reportable~~ based on an annual review and analysis of epidemiological data. See the following definitions and pathogen lists for each species or species group.

A. Exotic: Those infectious agents that have not been detected in Maine as of the effective date of this rule or that are the subject of an eradication program.

B. ~~Reportable~~ Endemic/Limited Distribution: Those infectious agents of regulatory concern whose geographic distribution within the State of Maine is not fully known, but whose presence may pose a threat to wild or farmed marine organisms. ~~Pathogens classed as reportable based on available information are specified for each species group.~~

~~C. Non-reportable: Those infectious agents currently recognized to occur with predictable regularity in the State of Maine with only minor fluctuation in frequency over time, and whose presence does not pose substantial risks to wild or farmed marine organisms.~~

~~22~~ 25. **"Pleuronectid"** means fish of the family Pleuronectidae.

~~23~~ 26. **"Prevalence"** means the number of detectable cases of disease (or disease agents) present in a population.

27. **"Approved quarantine facility"** means a facility that the Commissioner has determined is designed, built and operated in a manner that adequately prevents the introduction of pathogens of regulatory concern or the spread of disease into waters outside the facility.

~~24~~ 28. **"Salmonid"** ~~Fish~~" means fish of the family Salmonidae.

~~25~~ 29. ~~Shellfish.~~ **"Shellfish"** means clams, quahogs, oysters, mussels and scallops.

~~26~~ 30. **"Standard methods"** means pathogen detection methods specified in the Blue Book and/or in OIE publications, unless other standards are specifically approved by the Commissioner.

24.02 Permit to Import American Lobsters

Importation and introduction of American lobsters (*Homarus americanus*) are allowed by blanket permit under these regulations. No specific permit issued under §24.05 is required for such activity.

24.03 Prohibited Activity

It shall be unlawful to import for introduction or to introduce ~~into any coastal waters~~ any live marine organisms whether indigenous or nonindigenous, without a permit issued by the ~~commissioner~~ Commissioner. It shall also be unlawful to possess any live marine organism which has been imported for introduction or introduced without a permit issued by the ~~commissioner~~ Commissioner.

24.04 Aquatic Animal Health Technical Committee

An Aquatic Animal Health Technical Committee (AAHTC) shall be established jointly by the Commissioners of the Departments of Inland Fisheries and Wildlife and the Department of Marine Resources to provide advice to maintain optimum health among Maine's aquatic resources and to safeguard wild and cultured organisms from the introduction or dissemination of infectious organisms.

1. Composition and Selection

   The composition and selection of the Aquatic Animal Health Technical Committee shall reflect the interdisciplinary expertise required to address aquatic animal health issues. All members of the Aquatic Animal Health Technical Committee shall be qualified fish health inspectors or qualified professionals in the aquatic animal health field.

   A. There shall be a total of three members representing the public resource agencies; the Maine Department of Inland Fisheries and Wildlife, the Maine Department of Marine Resources and the Maine Department of Agriculture, ~~Food and Rural Resources~~ Conservation, and Forestry.

   B. There shall be one member representing the United States Fish and Wildlife Service.

   C. There shall be one member representing the National Oceanic and Atmospheric Administration - National Marine Fisheries Service (NOAA Fisheries).

   D. There shall be one member representing the U.S. Department of Agriculture, Animal and Plant Health Inspection Service.

   E. There shall be two members at large of which at least one shall be from academia.

   F. There shall be two additional members with experience in commercial finfish culture.

   G. There shall be two additional members with experience in commercial shellfish culture.

   H. The chair shall be elected by a majority vote of the Aquatic Animal Health Technical Committee.

2. Responsibilities

   A. Responsibilities of the Aquatic Animal Health Technical Committee shall be to provide technical advice to the Commissioners in the following areas:

      (1) Procedures for disease and pathogen surveillance and health monitoring among aquatic animal resources.

      (2) Diagnostic protocols and standards.

      (3) Criteria for biosecurity, quarantine, animal destruction and facility clean up.

      (4) Control of a disease outbreak.

      (5) Following annual review and analysis of epidemiological data provide recommendations to the Commissioners regarding the classification and testing requirements for Pathogens of Regulatory Concern.

   B. The Aquatic Animal Health Technical Committee shall also:

      (1) Review and make recommendations to the Commissioners on pathogen surveillance and the health status of aquatic animal resources.

(2) Actively pursue the development of research programs for addressing the aquatic animal health issues facing the State's resources.

(3) Serve as a technical resource for aquaculture facility managers to improve management and husbandry practices.

24.05 Permit Application for Marine Organisms

Any person who wishes to import for introduction or introduce any ~~shellfish or finfish~~ marine organism or to possess any such ~~shellfish or finfish~~ organism, must apply for a permit from the ~~commissioner~~ Commissioner. Application for a permit shall be submitted on forms supplied by the ~~commissioner~~ Commissioner and shall contain all information required by the ~~commissioner~~ Commissioner, including without limitation the following:

1. name, address, e-mail home and business phone of the applicant;

2. species, life cycle stage and quantity of ~~shellfish or finfish~~ marine organism to be imported or introduced;

3. area of origin, including name and address of hatchery, if any;

4. area of proposed import or introduction, including name and address of hatchery or ~~fish cultural~~ culture facility, if any;

5. date of proposed import or introduction;

6. nature, duration and purpose of import or introduction;

7. if a nonindigenous species, an explanation of the known habitat and biological and behavioral characteristics of the species, as well as the effects on epifauna and associated organisms; and

8. a statement of examination by a state, federal or Department of Marine Resources approved aquatic pathogen detection facility indicating its findings and certifying that the marine organisms to be imported or introduced are free of any infectious or contagious disease agents or pests or parasites based on standard methods and techniques of pathogen detection.

   In the alternative, if a person wishes to import or introduce any marine organism that is unable to be certified as free of one or more pathogens of regulatory concern, the applicant must provide a description of the proposed quarantine facility to allow the Commissioner to determine whether or not the quarantine facility will adequately prevent the introduction of pathogens of regulatory concern into waters outside the quarantine facility.

9. A valid fish health inspection report issued by a fish health inspector which meets the requirements of these regulations and any applicable ~~New England~~ Northeast Fish Health Committee Guidelines.

24.06 Permit Application for Shellfish Used as ~~Brood Stock~~ Broodstock in Hatcheries

Any person who wishes to import or introduce any live shellfish for use as ~~brood stock~~ broodstock in a shellfish hatchery or to possess any such shellfish must apply for a permit from the ~~commissioner~~ Commissioner. Applications shall contain all information required by the ~~commissioner~~ Commissioner including without limitation the information required by 24.05 ~~A~~ 1 through ~~G~~ 7 and a description of the physical facilities and production protocols associated with the quarantine of ~~brood stock~~ broodstock required by Section 24.07. Permits may be issued annually. A permit may allow the importation of single or multiple lots of shellfish for use as ~~brood stock~~ broodstock in shellfish hatcheries from the area(s) designated in the permit during the period the permit is valid.

24.07 Requirements for Shellfish Held as ~~Brood Stock~~ Broodstock

Any person issued a permit under 24.06 shall hold such ~~brood stock~~ broodstock in an approved quarantine facility within the hatchery. Effluent from hatchery tanks or other equipment holding ~~brood stock~~ broodstock must be treated by chlorination to achieve a free chlorine concentration of at least 50 parts per million at least two (2) hours after application prior to discharge. Daily records shall be maintained regarding the use of the chlorination treatment system that indicate the time and date of chlorine application and include chlorine test papers used to test results.

24.10 Permit Issuance Criteria ~~For~~ for Shellfish

1. The ~~commissioner~~ Commissioner may grant a permit to import for introduction or introduce shellfish, or to possess such shellfish, only if ~~he~~ the Commissioner finds to a reasonable degree of certainty that those actions will not endanger the indigenous marine life or its environment.

2. In determining whether to issue a permit the ~~commissioner~~ Commissioner shall consider the probable effects of the introduction of the shellfish into the recipient area, including, but not limited to:

   A. the effects of any previous introduction of the same or a similar species in Maine or other areas;

   B. the relationship of the species of marine organism to be introduced with other members of the recipient area ecosystem; and

   C. the potential effects of infectious or contagious diseases, pests or parasites that might be associated with the species of marine organism to be introduced upon other members of the ecosystem of the recipient area.

3. Shellfish from the restricted areas listed in Paragraph D below shall be presumed to carry the infectious diseases, pests or parasites listed in Appendix A, unless an applicant produces sufficient evidence to rebut this presumption. The presumption may be rebutted by pathologic examination satisfactory to the Department or by a demonstration that the shellfish to be imported, introduced, or possessed have been raised in a closed-system hatchery free of the infectious or contagious diseases found in the coastal waters of the restricted area. Shellfish from areas not listed in Paragraph D must meet the requirements of Section 24.05 and demonstrate either that the shellfish do not carry the infectious disease, pests, or parasites listed in Appendix A or that the shellfish have been raised in a closed-system hatchery free from infectious or contagious diseases.

4. The following geographical areas shall be considered restricted areas for the particular species listed:

   A. New York. The areas of New York State known as Great South Bay, Micox Bay and Fisher's Island on the north shore of Long Island shall be a restricted area for all species of shellfish;

   B. Connecticut. The area of Connecticut known as New Haven Harbor and the federal Milford Hatchery in Milford, Connecticut shall be a restricted area for all species of shellfish;

   C. Rhode Island. The area of Rhode Island known as Charlestown Pond shall be a restricted area for all species of shellfish;

   D. Massachusetts. The areas of Massachusetts known as Wellfleet Harbor, Cotuit Bay, Oyster River and Wareham River shall be a restricted area for all species of oysters;

   E. New Hampshire. The State of New Hampshire shall be a restricted area for all species of oysters;

F. Maine. All coastal waters within the State of Maine shall be a restricted area for the European Oyster, (*Ostrea edulis).* All territorial waters in the areas listed below shall be a restricted area for the American oyster, *(Crassostrea virginica)* greater than 3 mm in size:

1) Between Ocean Point, Linekin Neck, Boothbay to Pemaquid Point, Bristol

2) North of a line beginning at the southernmost point on Linekin Neck, Boothbay and continuing southwest to the southern tip of Kennebec Point, Georgetown, including the Sheepscot, Back, and Cross Rivers, and all tributaries.

3) East of the Route 127 bridge between Arrowsic and Georgetown (Back River).

4) East of the Route 127 bridge between Sasanoa Point, Woolwich and Preble Point, Arrowsic (Sasanoa River).

G. New Jersey. The State of New Jersey shall be a restricted area for American oysters;

H. Delaware, Virginia, North Carolina, South Carolina, Florida and Louisiana. These states shall be a restricted area for American oysters;

I. Maryland. This State shall be a restricted area for American oysters and soft-shell clams;

J. California. The areas of this State known as Mono Bay, Elkhorn Slough, Drakes Estero, Tomales Bay and Humbalt Bay shall be a restricted area for Pacific and European oysters;

K. Washington. The area of this State known as Willapa Bay shall be a restricted area for Pacific oysters and mussels;

L. Canada, British Columbia. The areas of this province known as Henry Bay, Denmon Island, Seal Island, Comax Harbor, Lady Smith Harbor, Crofton, Saltair, Sibell and Nanoose Bays shall be a restricted area for Pacific oysters;

M. Canada, Maritime Provinces. This area of this country shall be a restricted area for American oysters, European oysters, blue mussels and hard-shell clams.

N. Cuba, Venezuela, Mexico and Brazil. These countries shall be restricted areas for all species of oysters;

O. Netherlands and Denmark. These countries shall be restricted areas for European oysters;

P. France. This country shall be a restricted area for all species of oysters;

Q. Japan. This country shall be a restricted area for Pacific oysters;

R. Australia. This country shall be a restricted area for *Crossostrea commercialis.*

5. The ~~commissioner~~ Commissioner may include any permit conditions necessary to protect indigenous marine life or its environment, including, but not limited to, quarantine of ~~brood-stock~~ broodstock in closed system hatcheries in recipient areas, quarantine of F1 generation individuals in isolation from ~~brood-stock~~ broodstock and small-scale introduction of F2 generation individuals into recipient areas with continuing disease study.

24.15 Permit Issuance Criteria for Marine Organisms Other than Shellfish

1. The ~~commissioner~~ Commissioner may grant a permit to import for introduction or introduce any marine organism other than shellfish, or to possess such an organism, only if he finds to a reasonable degree of certainty that those actions will not endanger the indigenous marine life or its environment.

2. In determining whether to issue a permit, the ~~commissioner~~ Commissioner shall consider the potential effects of the introduction of the marine organism into the recipient area, including, but not limited to:

   A. the effects of any previous introduction of the same or a similar species into the ~~state~~ State of Maine or the effects of any previous introduction of the same or a similar species into similar ecosystems elsewhere;

   B. the relationship of the species of marine organism to be introduced with other members of the recipient area ecosystem; and

   C. the effects of infectious or contagious diseases, pests or parasites which might be associated with the species of marine organism to be introduced upon other members of the ecosystem of the recipient area.

3. The ~~commissioner~~ Commissioner may include any permit conditions necessary to protect indigenous marine life or its environment, including but not limited to, quarantine of ~~brood stock~~ broodstock, inclusive of effluent treatment, in the recipient area, quarantine of first generation progeny individuals in isolation from the ~~brood stock~~ broodstock and small-scale introduction of second generation progeny individuals into the recipient area with continuing disease study.

4. The ~~commissioner~~ Commissioner may accept certifications provided by the Maine Department of Inland Fisheries and Wildlife that an import for introduction or introduction of finfish ~~imported for introduction~~ will not endanger the indigenous marine life or its environment.

5. In determining whether to issue a finfish permit the ~~commissioner~~ Commissioner shall also follow the ~~New England~~ Northeast Fish Health Committee Guidelines which set forth the essential requirements for the prevention and control of finfish diseases. These include a system for inspecting fish culture facilities and the technical procedures to be used.

24.16 Finfish Control

1. Definitions:

   A. **"Lot"** means the following:

      (1) A lot for size groups 1, 2, and 3 (non-brood facilities) is defined as fish of the same species and age that originated from the same spawning stock and have shared a common water supply continuously throughout their life history. For the purposes of marine fish species that spawn over an extended period of time, a lot will comprise fish that were produced over the course of six months. See each species section for size group definitions.

      (2) A lot for size group 4 is defined as fish of the same species that originated from the same spawning stock and share a common water supply, but several age groups (e.g., 3, 4, and 5 year old brood fish) may be combined to form a representative composite lot for sampling.

   B. **"Production stock"** means finfish of size groups 1, 2, and 3.

   C. **"Qualified source/hatchery"** means an established source/hatchery that has had 3 consecutive annual inspections in which pathogens as described in Chapter 24.21(1)(D), 24.32(3), and 24.34(3) have not been detected; or a new hatchery that has had 3 successive negative annual inspections over a continuous 2 year period.

   D. **"Quarantine",** when applied to rules governing marine net-pen facilities, means:
   that there must be no movement of live fish off of or onto the site;
   that no visitors may be allowed on the site except for necessary fish health personnel;
   that a biosecurity program approved by the Commissioner must be instituted at the site; and

that disposition of deceased and quarantined fish must be approved by the Commissioner.

E. **"Reproductive fluids"** means testicular and ovarian fluids.

F. **"Restriction"** means that there must be no movement of live fish off of or onto the site; that disinfection protocols and biosecurity must be instituted at the site.

G. **"Spawning broodstock"** means a lot of ~~sexually~~ reproductively mature finfish whose gametes will be incubated at fish culture facilities within Maine.

H. Transfer Permits and Reports means:

(1) **"Annual Fish Health Inspection Report**" means the letter from the Inspector acknowledging that all lots of fish have been inspected according to procedures outlined in Chapter 24.21(1)(E), 24.32(4) and 24.34(4). For facilities which conduct inspections more frequently, the annual inspection shall be a compilation of all results for the year. The Fish Health inspection report shall include an itemized account of results.

(2) **"Fish Health Inspection Report"** means a letter from the Inspector acknowledging that a specific lot or lots of fish have been inspected according to procedures outlined in Chapter 24.21(1)(E), 24.32(4) and 24.34(4). The Fish Health inspection report shall include an itemized account of results.

(3) **"Annual Fish Culture Facility Health Report"** means a letter from the Commissioner stating the health status of any Fish Culture Facility that requires an annual Fish Health Inspection Report. The Fish Culture Facility Health Report shall be based upon the findings of Annual Fish Health Inspection Reports, the ~~New England~~ Northeast Fish Health Committee Guidelines and any other fish health inspection reports.

(4) **"Transfer permit"** means the permit issued by the Commissioner that authorizes the recipient to transfer finfish to designated geographical area(s) in the coastal waters of Maine during a specified time period. A transfer permit may not be issued until the Department has reviewed the Annual Fish Culture Facility Health Report.

(5) **"Marine Transfer permit"** means the permit issued by the Commissioner that authorizes the recipient to transfer live finfish between marine ~~sites~~ net-pen facilities. A marine transfer permit does not require additional fish health testing requirements unless the transfer is requested between marine fish health zones.

2. A copy of any required permit shall accompany the finfish shipment at all times, and must be presented upon request to department employees.

3. For finfish species for which ~~exotic, reportable and non-reportable diseases~~ pathogens of regulatory concern are not specified elsewhere in these rules, any time a lot of such fish is diagnosed as having a specific disease or disease agent which can be diagnosed or detected in fifty percent of the mortality or moribund individual fish in an affected container, and which results in an average daily mortality of at least one-half of one percent of the affected individual fish for five or more days in any thirty day period, the permit holder shall notify the Department in writing and by telephone within 48 hours.

4. The permit holder shall maintain records that document mortalities and any treatments used to control those mortalities. These records shall be maintained for 5 years and be made available to the Department upon request. These records shall be kept on forms supplied by the Commissioner.

5. Consequences/Action Plan

A. Exotic Pathogen

(1) When any exotic pathogen of regulatory concern is confirmed at any fish culture facility in Maine as a result of active or passive surveillance, the marine organism culture facility owner shall notify the Commissioner in writing and by telephone within 24 hours of the confirmation. In addition, within 24 hours of confirmation of the detection of any exotic pathogen ~~or~~ of regulatory concern, all fish on the site must be restricted. The report to the Commissioner must include, as a minimum:

(a) Species of fish affected;
(b) Size group and age of fish;
(c) Pathogen and whether or not it is clinical;
(d) Prevalence;
(e) Actions being taken to contain or eradicate the pathogen; and
(f) Proposed actions to restore the facility to a qualified source/hatchery.

(2) ~~The Commissioner shall review the relevant facts and may consult with the Aquatic Animal Health Technical Committee, relevant State and Federal agencies, and other professionals,~~ The Commissioner shall review the report, the Northeast Fish Health Committee Guidelines and may consult with the Aquatic Animal Health Technical Committee, relevant state and federal agencies, and other professionals, and make a decision concerning the remedial action to be taken, if any, in accordance with applicable sections of these regulations. Consideration will be given to certain risk factors including but not limited to:

(a) Risk to the aquaculture industry;
(b) Risk to wild stocks;
(c) Feasibility of eradication by stock destruction;
(d) Time frame and degree of pathogen spread (i.e., local vs. regional);
(e) Final intended disposition of infected stocks; and
(f) Public health ramifications.

(3) Following completion of the risk assessment, the Commissioner may order one or more of the following remedial actions at the affected facility and throughout an area which is determined to pose a risk of exposure to the exotic pathogen of regulatory concern, after consideration of the risk factors in Chapter 24.16(5)(A)(2).

(a) Harvest and sale of processed fish;
(b) Destruction of the stock and proper disposal to minimize release of pathogen(s);
(c) Stocking of the fish if such action possesses no or minimal risk to wild populations;
(d) Re-testing of stock for pathogen;
(e) Treatment of fish and re-test;
(f) Quarantine and continued quarantine of fish for purpose of study or salvage of gametes; or
(g) Other actions determined to be appropriate by the Commissioner upon consultation with the Aquatic Animal Health Technical Committee.

B. ~~Reportable~~ Enzootic/Limited Distribution Pathogens

(1) When any ~~reportable~~ enzootic/limited distribution pathogen of regulatory concern is confirmed at any fish culture facility in Maine as a result of active or passive surveillance, the marine organism culture facility owner shall notify the Commissioner within 14 days after confirmation of the disease agent and prior to movement or transfer. The report to the Commissioner must include, at a minimum:

(a) Species of fish affected;
(b) Size group and age of fish;
(c) Pathogen and whether it is clinical or non clinical;
(d) Prevalence;
(e) Actions being taken to contain or eradicate the pathogen; and
(f) Proposed actions to restore the facility to a qualified source/hatchery.

(2) The Commissioner shall review the report, the ~~New England~~ Northeast Fish Health Committee Guidelines and may consult with the Aquatic Animal Health Technical Committee, relevant state and federal agencies, and other professionals, and make a decision concerning movement or transfer of the fish.

24.20 Hearing

A hearing on a permit application is not required except that a hearing shall be required where an applicant requests permission to import for introduction, introduce, or possess a nonindigenous species which has not been introduced previously under a Department of Marine Resources permit.

24.21 Salmonid Fish Health Inspection Regulations

1. Inspection Regulations

A. Prohibited Activity

(1) Except as provided in this subsection, it is unlawful to transfer ~~live~~ salmonid ~~gametes or~~ finfish to any fish culture facility in Maine or stock salmonid finfish ~~or gametes~~ into the coastal waters of Maine that do not meet the requirements of these rules.

The Commissioner may, at his discretion and in consultation with the AAHTC, issue a permit to import or transfer finfish from sources or facilities that do not meet the requirements of these rules to an approved quarantine facility. Transfer from an approved quarantine facility, or a change in operation to that which is less biosecure, may be permitted if post-import testing provides satisfactory evidence of freedom from those pathogens of regulatory concern for which evidence of freedom was not satisfied at the time of import.

(2) No clinically diseased salmonid finfish shall be introduced into the coastal waters of Maine.

B. Definitions

For the purposes of these rules the following terms have the following meanings in addition to the definitions in Chapter 24.01 and 24.16(1):

(1) **"Size Group"** means:
Size Group 1: Fish less than or equal to 4 cm in length, commonly referred to as fry.
Size Group 2: Fish from 4 to 6 cm in length, commonly referred to as fingerlings.
Size Group 3: Non-brood fishes greater than 6 cm in length, commonly referred to as yearlings/adults, which are not being held as broodstock.
Size Group 4: Sexually mature fish used as broodstock.

C. Compliance Reporting Requirements, Reporting and Permits

(1) Inspections

(a) Any person wishing to import, possess, or sell ~~live~~ salmonid~~s or gametes~~ finfish for the purposes of stocking into coastal waters of Maine shall provide a fish health inspection report stating that such salmonid ~~fish or gametes~~ finfish have been inspected for all pathogens of regulatory concern before a permit to engage in such activity is issued.

(b) Live salmonid ~~fish or gametes~~ finfish taken from the wild shall be subject to isolation as defined in the ~~New England~~ Northeast Fish Health Committee Guidelines pending

the completion of inspection procedures outlined in Chapter 24.21(1)(E) and the issuance of a fish health inspection report.

(2) Any salmonid fish culture facility raising fish to be introduced into the coastal waters of Maine must submit the most current annual fish health inspection report on approved forms to the Department of Marine Resources prior to the sale and/or movement of such fish from the facility.

(3) Except as provided in Chapter 24.21 (1)(A)(1), any person applying for a permit to import ~~live~~ salmonid~~s or gametes~~ finfish into the State of Maine shall demonstrate that the finfish ~~or gametes~~ being imported are free from evidence of all pathogens of regulatory concern; and that the finfish ~~or gametes~~ are from a qualified source/hatchery. ~~which meets or exceeds the standards established in these rules; and that the source and facility have been free from evidence of all pathogens of regulatory concern for three years immediately preceding the permit application or a new hatchery that has had 3 successive negative annual inspections over a continuous 2 year period.~~ The Commissioner may prescribe additional fish health testing requirements for importation of salmonids or gametes into the State of Maine. A copy of the current approved transfer permit shall accompany the ~~fish or gametes~~ finfish during transfer.

Evidence of disease freedom for Ceratonova/Ceratomyxa shasta (ceratomyxosis), Myxobolus cerebralis (Whirling disease), and Tetracapsuloides byrosalmonae (PKD) may be considered satisfactory for meeting the requirements of a qualified source/hatchery, if importation will be in the form of embryos that have been iodine disinfected before and immediately after import, prior to the time of introduction to the waters of the receiving facility.

(4) Any person offering ~~live~~ salmonid~~s or gametes~~ finfish for sale or transferring ~~live~~ salmonid~~s or gametes~~ finfish to a source in Maine shall provide a current fish health inspection report to any customer or recipient of the fish. A copy of the current approved transfer permit shall accompany the ~~fish or gametes~~ finfish during transfer.

(5) ~~Live salmonid fish or gametes~~ Salmonid finfish transferred for the purposes of immediate harvest for human consumption~~,~~ or diagnostic inspection ~~or related laboratory research~~ shall not be subject to the provisions of these rules. Salmonids harvested for the purposes of human consumption shall be harvested, handled, processed, and transported using measures to minimize the introduction of infectious disease into Maine waters. The Aquatic Animal Health Technical Committee will serve as a technical resource in developing guidelines for biosecurity measures associated with harvesting, transport, and processing.

(6) ~~Live salmonid fish~~ Salmonid finfish may not be transferred between marine ~~sites~~ net-pen facilities without ~~an ocean site to ocean site~~ a marine transfer permit.

D. Testing requirements for Pathogens of Regulatory Concern

	Spawning Broodstock			Production Stock				
	Size Group 4			Size Group 1			Size Groups 2 & 3	
Inspection Testing Requirement	Exotic ~~Reportable~~	~~Endemic, limited distribution~~ Endemic/Limited Distribution ~~Reportable~~		Exotic ~~Reportable~~	~~Endemic, limited distribution~~ Endemic/Limited Distribution ~~Reportable~~		Exotic ~~Reportable~~	~~Endemic, limited distribution~~ Endemic/Limited Distribution ~~Reportable~~
Active Surveillance	VHSV IHNV ISAV-DEL	IPNV BKD		VHSV IHNV ISAV-DEL	IPNV		VHSV IHNV WD	BF BR IPNV

							ISAV-DEL	BKD
Passive Surveillance	OMV CS WD PKD SPDV Other	BF BR ISAV-HPR0 Other		OMV CS PKD SPDV Other	BF BR BKD ISAV-HPR0 Other		OMV CS PKD SPDV Other	ISAV-HPR0 Other

E. Inspection Procedure: The following procedures shall be carried out by an inspector, as defined in these regulations.

(1) ~~A fish culture facility inspection of all production lots shall be completed at least annually.~~ Qualified source/hatchery inspection: Except for approved quarantine facilities, those facilities which intend to serve as a qualified source/hatchery for import or transfer to other fish cultures facilities or that stock fish into the coastal waters of the State shall complete an inspection of all production lots at least annually.

(2) Fish health inspections shall be conducted at a time or times of the year conducive for the detection of pathogens and with regard to the age and size of fish and environmental conditions.

(3) A visual exam of all tanks/raceways to assess general health status shall be conducted during the annual inspection.

(4) Testing procedures for infectious agents shall be conducted according to requirements and methodologies approved by the Commissioner. Testing requirements for salmonids in the respective size groups shall be conducted according to Chapter 24.21(1)(D). For viral pathogens, the inspector shall test at the 95% confidence level, 5% prevalence per lot. For bacterial pathogens, the inspector shall test at 95% confidence level, 10% prevalence per lot. In order to detect evidence of the agent of Whirling Disease, the inspector shall sample sixty fish per facility or per water supply, if the facility has more than one water supply. Samples examined for evidence of Whirling Disease shall be of the most susceptible species and ages of fish available. For example, select brook or rainbow trout over brown trout or coho salmon. Select fish at least 5 months old if possible, as referenced in the Blue Book. If bacterial pathogens are negative for 3 consecutive annual inspections, then sampling levels may drop to 20% assumed prevalence for as long as sampling continues to test negative.

(5) Spawning Broodstock shall be tested within 30 days immediately before or after spawning for diseases of regulatory concern according to Chapter 24.21(1)(D).

(a) Reproductive fluids shall be sampled at the 100% level or lethal sampling at a 10% assumed prevalence up to a maximum of 30 fish and reproductive fluids a 2% assumed prevalence level. Reproductive fluids can be collected by trained facility personnel under the direction of the inspector using a specimen chain of custody form.

(b) Complete laboratory diagnostic testing (virology, bacteriology and parasitology) done on broodstock mortalities during a given year can be included if the lethal sampling option is chosen.

(6) Sample size:

(a) For viral and bacterial pathogens the number of samples to be collected from a given lot shall be based upon stratified random sampling which provides 95 percent confidence of detecting a pathogen with an assumed minimum prevalence of detectable infection of two to twenty percent as follows:

Minimum sample sizes for populations varying from 50 to infinity are as follows:

Assumed Prevalence:	2%	5%	10%	20%
Population or lot size	Size	of	Sample	
50	50	35	20	5
100	75	45	23	8
250	110	50	25	11
500	130	55	26	13
1,000	140	55	27	14
1,500	140	55	27	14
2,000	145	60	27	15
10,000	145	60	27	15
100,000 and any larger	150	60	30	15

The above sample sizes are the minimum number of fish to be tested and in situations where pathogens are suspected, additional samples shall be taken at the discretion of the fish health inspector. The method of collecting subsamples from rearing units to obtain a representative sample is left to the discretion of the inspector.

(b) Inspections shall be performed and samples collected by the inspector or a person working under his/her supervision. The inspector is responsible for all work performed.

(c) Pathogens as described in Chapter 24.21(1)(D) detected by passive surveillance between annual fish health inspections must be reported by the marine fish culture facility owner to the Commissioner at the time of inspection.

(d) Upon completion of the annual inspection of the fish culture facility, an inspection report will be issued to the marine fish culture facility owner or operator and the Commissioner. Upon receipt of the inspection report, the Department will review the report and may issue a transfer permit if the report meets the standards outlined in these rules.

(e) Lots of ~~fish and/or gametes~~ finfish ~~r~~eceived from qualified sources/hatcheries will not invalidate that fish culture facility's annual inspection status.

(f) Lots of ~~fish and/or gametes~~ finfish ~~r~~eceived from sources other than qualified sources/hatcheries that do not comply with Chapter 24.21(1)(C)(1) will invalidate the receiving fish culture facility's annual inspection status.

F. Pathogen list for Salmonids

1. Exotic pathogens include:

IHNV	Infectious Hematopoietic Necrosis Virus
VHSV	Viral Hemorrhagic Septicemia Virus
OMV	Oncorhynchus masou Virus
WD	Whirling Disease (Myxobolus cerebralis)
CS	Ceratomyxosis (Ceratomyxa shasta)
PKD	Proliferative Kidney Disease (PKX unclassified myxozoan)
ISAV-DEL	Infectious Salmon Anemia Virus (HPR-deleted variants)
SPDV	Salmonid Pancreatic Disease Virus
OTHER	Any ~~pathogen~~ agent not detected in Maine as of the effective date of these rules that produces a cytopathic effect in cell culture during inspection.

2. Reportable pathogens include:

ISAV HPR0	Infectious Salmon Anemia Virus (non-deleted variants)
IPNV	Infectious Pancreatic Necrosis Virus
BKD	Bacterial Kidney Disease (Renibacterium salmoninarum)
BF	Furunculosis (Aeromonas salmonicida)
BR	Enteric Redmouth (Yersinia ruckeri)
OTHER	Any agent that produces a cytopathic effect in cell culture during inspection.

~~3. Non-reportable pathogens include: those which are not listed above and which are currently recognized to occur with regularity in the State of Maine.~~

G. Special Salmonid Fish Health Inspection Regulations Relating to ISAV

(1) Affected Facilities
All marine salmonid finfish net pen culture facilities (finfish facilities), located within the coastal waters of the State of Maine, are subject to the requirements of this subsection. These requirements are in addition to the other requirements of Chapter 24.21.

(2) Mandatory surveillance and reporting
All holders of finfish aquaculture leases, or their designees, shall comply with these surveillance and reporting requirements. For those leaseholders that are participating in a United States Department of Agriculture (USDA) voluntary ISA control program, where conflicts exist between these rules and voluntary ISA control program standards or rules the USDA standards or rules shall govern.

(a) Surveillance
Surveillance for Infectious Salmon Anemia Virus (ISAV) in accordance with this subsection (24.21(1)(G)) shall be conducted by inspectors designated by the Maine Department of Marine Resources. ~~For each sampling period the date(s) of sampling will be communicated to the Department within 48 hours of the initiation of sampling at the respective site(s).~~ All analytical tests shall be completed within 14 days of the date of sampling and records made available to the Department upon request. All samples must have a clear written chain of custody from the inspector to the accredited analytical laboratory conducting the tests.

(b) Testing procedures

(i) Level of Surveillance
The level of surveillance shall be consistent with the most recent available version of the United States Department of Agriculture, Animal and Plant Health Inspection Service's "Infectious Salmon Anemia Program Standards" (ISA Standards)~~, revised by the ISA Technical Board January 2008~~. Sampling must be conducted monthly for all active salmonid facilities. ~~Monthly sampling should include a minimum of 10 fish when possible and up to a maximum of 30 moribund, recently dead, or live fish exhibiting signs or lesions consistent with ISAV.~~ The Commissioner may authorize an alternative sampling protocol where conditions warrant.

The Commissioner may require more frequent testing for specific finfish facilities if a suspected positive case of ISAV is detected.

(ii) Sample Classification
Reverse transcriptase polymerase chain reaction (RT-PCR) shall be the primary screening diagnostic test utilized to detect the presence of ISAV. Indirect fluorescence antibody test (IFAT) impression smears will be acetone-fixed and archived. IFAT slides corresponding to any tissue sample testing positive by RT-PCR will subsequently be tested. Classification of samples with respect to ISAV detection shall conform to the ISA Standards. In the event of a positive ISAV diagnostic procedure, diagnostic tests to resolve the classification of suspect or unconfirmed samples using material from the positive tests or remaining sample

material must be initiated within 24 hours of any positive diagnostic procedure. Viral culture is required using fish collected during a 7-day reinspection for suspect finfish facilities. Genetic sequencing may be warranted following RT-PCR positive findings. The Commissioner may require specific tests as necessary to resolve the classification of suspect or unconfirmed samples.

(c) Completion and submission of results
Surveillance results, regardless of whether ISAV was detected (positive or negative results), shall be reported in written form via email, fax or hand-delivery to the Department, within 24 hours of their completion. Each report shall include, at a minimum: Inspector's name, date sampled, DMR lease site identification code, ~~site and~~ pen(s) sampled, year class status of salmonids on the site, size group, name of the lab conducting each analysis, the analytical test(s) used, and copies of original laboratory test results.

(d) Transfer permits
All transfer permit requests (Chapter 24.16(1)(H)(4 and 5)) must include the most current ISAV status and a date of that status for the finfish facility to which the fish are to be transferred.

Marine to marine transfers are prohibited, unless an exemption is provided for on a case-by-case basis by the Commissioner. Exemptions shall only be granted for unusual circumstances that do not increase the likelihood of ISAV transmission between finfish facilities.

(e) Participation
Participation shall be in the USDA ISA surveillance and monitoring program, unless the Commissioner reviews and approves a company ISA surveillance or indemnification program.

~~(f) Contact information~~
~~Commissioner: email george.lapointe@maine.gov~~
~~Aquaculture Policy Coordinator: (request via phone contact listed)~~
~~Street address: Baker Building – 2 Beech St. St., Hallowell, Maine 04347~~
~~Mailing address: 21 State House Station, Augusta, Maine 04333-0021~~
~~Phone (207) 624-6550 Fax (207) 624-6024~~

(3) Consequences / Action Plan
Following a confirmed positive case of ISAV, the Commissioner shall take action according to Chapter 24.16(5)(A) Exotic Diseases. This action plan shall include remedial action(s) including further diagnostic procedures. In the Commissioner's sole discretion, remedial action requirements may be based on the facility's existing ISAV action plan.

H. Restrictions on Vessel & Equipment Movement

(1) Affected Vessels and Equipment
This subsection applies to all vessels, service equipment and net pens utilized to conduct finfish aquaculture operations and activities including, but not limited to harvest boats, well boats, personnel transport vessels, dive and mortality-handling vessels, and feed transport barges. It does not apply to recreational or commercial vessels not engaged in aquaculture.

(2) Biosecurity Audits & Disinfection Protocols

All vessels, service equipment and net pens involved in aquaculture activities will be required to undergo an initial ~~and~~ biosecurity audit by persons authorized by the Department when they are put into operation. Biosecurity audits, including timely follow-ups if needed to verify compliance with the initial audit's findings, shall be undertaken on a semi-annual basis in Marine Fish Health Zone, Area 1 and annually outside of Area 1. An initial audit must take place within 30 days of the first day of operation.

Authorized auditors have the authority to specify remedial action for deficiencies revealed in an initial audit. The Commissioner shall determine whether sufficient remedial action was taken by the marine ~~fish culture~~ net-pen facility owner after reviewing the initial and follow-up audit results.

All completed initial and follow-up audits shall be placed on file with the Department no later than 30 days following their completion. In order to be deemed acceptable, audits conducted in Canada must be signed by either the appropriate provincial authorities or an accredited veterinarian.

All vessels, service equipment, and net pens involved in aquaculture must be routinely disinfected according to the disinfection protocols ~~as~~ established in ~~Appendix G of the Maine Aquaculture Association, Finfish Bay Management Agreement, dated January 2002, or as authorized by the Department.~~ the ISA Standards (most recent available edition).

(3) Aquaculture Vessel, Service Equipment, and Net Pen Movement Restricted

Vessels, service equipment and net pens are prohibited from traveling west of the restricted area (Chapter 24.21(1)(H)(5)) unless exempted under Chapter 24.21(1)(H)(5)(a). Vessels, service equipment and net pens located outside the restricted area are prohibited from traveling into or through the restricted area unless exempted under Chapter 24.21(1)(H)(5)(a).

Vessels, service equipment and net pens are not prohibited from moving between the restricted area and Canadian waters, provided they do not travel west of the restricted area in order to do so.

However, there can be no movement of vessels, service equipment or net pens between either confirmed or suspected ISA or ISAv positive sites or bay management areas and Maine finfish aquaculture facilities without an authorization as described below.

All vessel operators shall maintain a log that clearly indicates all transit points of the vessel, including aquaculture site locations and bay management areas, disease status of the aquaculture site locations and bay management areas when known, and dates of all transit points. This log shall also include the date and manner of all disinfections conducted of the vessel.

At the Department's request, the log shall be submitted to the Department prior to entering the restricted zone defined below in Chapter 24.21(1)(H)(5) in order that the Department may verify the log information and the disease status of any of the sites or bay management areas with the appropriate authorities.

Pending review of the log, no vessel may enter the restricted zone as defined below in Chapter 24.21(1)(H)(5). After review of the log, vessels, service equipment, or net pens determined to have tended or visited any sites or bay management areas designated as being either confirmed or suspect for the presence of ISA or ISAv shall be subject to a required disinfection which may include below the waterline disinfection. For those vessels that have transited through a confirmed or suspect bay management area, the Department shall consider the specific routes and the present status of each site within the bay management area in determining the required disinfection.

Fish harvested as a result of an eradication order or from an aquaculture site designated as Category 2, 3, 4, or 5 as described in the United States Department of Agriculture's, Animal Plant Health Inspection Service's "Infectious Salmon Anemia Program Standards" (~~January 2008 revision~~ most recent available edition) or sites or bay management areas designated as confirmed or suspect by the Department for ISA or ISAV shall not be transported into or out of the restricted area by vessel unless authorized by the Department.

Such authorization shall require a risk evaluation be conducted by the Department and a complete disinfection and transit plan be approved by the Department prior to any transport of harvested fish.

~~To determine if a site or bay management area is designated as confirmed or suspect by the Department, see staff contact information in Chapter 24.21(1)(G)(2)(f).~~

(4) Prohibition on net movement between sites

Nets shall not be moved between finfish facilities. The movement of nets from finfish facilities to on-shore cleaning facilities is allowed provided the nets are contained.

(5) Restricted Area

These regulations apply to all vessels, service equipment and net pens utilized to conduct finfish aquaculture operations and activities located in Marine Fish Health Zone, Area 1 (Chapter 24.01(~~15~~ 18)(A)). ~~The eastern line of Area 1 is defined from the head of tide on the St. Croix River and International Boundary Line Canada and the U.S. (Maine). The western line of Area 1 is defined from West Quoddy Head Lighthouse extending bearing 40° magnetic to the International Boundary Line Canada and the U.S. (Maine).~~

(a) Exemptions

Vessels, service equipment and net pens having undergone an initial and follow-up biosecurity audits maintained on a semi-annual basis, by a person authorized by the Commissioner, may be granted an exemption to the movement restrictions following approval by the Commissioner. Exemption requests must include biosecurity audit results, including any follow-up audit and be submitted by the vessel owner or operator to the Commissioner in writing, see contact information above under Chapter 24.21(1)(G)(2)(f). An exemption document must be available for inspection on an exempted vessel, service equipment and net pens at all times and displayed according to the Commissioner's instructions.

24.23 Salmon Racks Prohibited

It is unlawful to introduce into the coastal waters of Maine any dead salmonid fish species or salmon remains, parts or viscera.

A. Exception.
This section shall not apply to commercially prepared salmon eggs used for bait.

24.30 Marine Fish Health Inspection Regulations

1. Prohibited Activity

A. Except as provided in this subsection, it is unlawful to transfer ~~live marine fish gametes or fish~~ marine finfish to any fish culture facility in Maine or stock marine ~~fish or gametes~~ finfish into the coastal waters of Maine that do not meet the requirements of these rules.

The Commissioner may, at his discretion and in consultation with the AAHTC, issue a permit to import or transfer finfish from sources or facilities that do not meet the requirements of these rules to an approved quarantine facility. Transfer from an approved quarantine facility, or a change in operation to that which is less biosecure, may be permitted if post-import testing provides satisfactory evidence of freedom from those pathogens of regulatory concern for which evidence of freedom was not satisfied at the time of import.

B. No clinically diseased finfish shall be introduced into the coastal waters of Maine.

2. Definitions

For the purposes of these rules the following terms have the following meanings:

A. Broodstock Sources:

(1) **"Wild Caught Broodstock"** means fish that are removed from the coastal waters and transferred to a land-based culture facility for use as broodstock.

(2) **"Hatchery-based Broodstock"** means fish that originate from and never leave a culture facility, and are selected to become broodstock.

(3) **"Marine-site Cultured Broodstock"** means fish that are cultured in the coastal waters and spawned in the coastal waters or transferred to a land-based culture facility for use as broodstock.

3. Compliance Reporting Requirements, Reporting and Permits

A. Inspections

(1) Any person wishing to import, possess, or sell ~~live fish or gametes~~ marine finfish for the purposes of stocking into coastal waters of Maine shall provide a fish health inspection report stating that such ~~fish or gametes~~ finfish have been inspected for all diseases of regulatory concern before a permit to engage in such activity is issued.

(2) ~~Live fish or gametes~~ Marine finfish taken from the wild shall be subject to quarantine, in a facility approved by DMR, for at least 90 days pending the completion of inspection procedures and the issuance of a fish health inspection report. Any mortality that occurs during collection or transport and a representative sample of the ~~live fish or gametes~~ finfish should be selected during the movement event for testing as prescribed for size group 2 of the relevant species.

B. Any fish culture facility raising finfish to be introduced into the coastal waters of Maine must submit the most current annual fish health inspection report on approved forms to the Department of Marine Resources prior to the sale and/or movement of such finfish from the facility.

C. Except as provided in Chapter 24.30(1)(A), any person applying for a permit to import ~~live marine fish or gametes~~ marine finfish into the State of Maine shall demonstrate that the ~~fish or gametes~~ finfish being imported are free from evidence of all diseases of regulatory concern, and originate from a ~~source~~ qualified source/hatchery. ~~which meets or exceeds the standards established in these rules; and that the source and facility have been free from evidence of all diseases of regulatory concern for three years immediately preceding the permit application; or (if a new hatchery), has had 3 successive negative annual inspections over a continuous 2 year period.~~ The Commissioner may prescribe additional fish health testing requirements for importation of ~~fish or gametes~~ finfish into the State of Maine. A copy of the current approved transfer permit shall accompany the ~~fish or gametes~~ finfish during transfer.

D. Any person offering ~~live fish or gametes~~ finfish for sale or transferring ~~live fish or gametes~~ finfish to a source in Maine shall provide a current fish health inspection report to any customer or recipient of the fish. A copy of the current approved transfer permit shall accompany the ~~fish or gametes~~ finfish during transfer.

E. ~~Live fish or gametes~~ Finfish transferred for purposes of immediate harvest for human consumption~~,~~ or diagnostic inspection ~~or related laboratory research~~ shall not be subject to the provisions of these rules. ~~Fish~~ Finfish harvested for the purposes of human consumption shall be harvested, handled, processed and transported using measures to minimize the introduction of infectious disease into Maine waters. The Aquatic Animal Health Technical Committee will serve as a technical resource in developing guidelines for biosecurity measures associated with harvesting, transport and processing.

F. ~~Live fish~~ Finfish may not be transferred between marine ~~sites~~ net-pen facilities without ~~an ocean site to ocean site~~ a marine transfer permit.

24.32 Gadids (Fish in the family Gadidae)

1. Definitions

For the purposes of these rules the following terms have the following meanings:

~~A. "Lot" means the following:~~

~~(1) A lot for size groups 1 and 2 is defined as Gadid fish of the same species and age that originated from the same spawning stock and share a common water supply.~~

~~(2) A lot for size group 3 is defined as Gadid fish of the same species that originated from the same spawning stock and share a common water supply, but several age groups (e.g., 3, 4, and 5 year old brood fish) may be combined to form a representative composite lot for sampling and/or veterinary monitoring.~~

~~B~~A. **"Production stock"** means Gadid fish of size groups ~~1 and 2~~ 1, 2 and 3.

~~C~~B. **"Size Groups"** means:
"Size Group 1": Larval period and juvenile size range of ≤ 4 cm in length.
"Size Group 2": Juvenile ≥ 4 cm in length and yearlings.
"Size Group 3": Production fish greater than one year old.
"Size group 4": Fish set aside to be used as broodstock upon maturity.

2. Pathogen list for Gadids

A. Exotic pathogens include:

IHNV	Infectious Hematopoietic Necrosis Virus
VHSV	Viral Hemorrhagic Septicemia Virus
ISAV-DEL	Infectious Salmon Anemia Virus (HPR-deleted variants)
GID	*Francisella species* – granulomatous inflammatory disease
La02β	*Listonella (Vibrio) anguillarum* serotype and 02 beta
OTHER	Any ~~pathogen~~ agent not detected in Maine as of the effective date of these rules that produces a cytopathic effect in cell culture during inspection.

B. ~~Reportable~~ Endemic/Limited pathogens include:

IPNV	Infectious Pancreatic Necrosis Virus
ISAV-HPR0	Infectious Salmon Anemia Virus (non-deleted variants)
BF	Furunculosis (*Aeromonas salmonicida*) typical and atypical
Nodavirus:	VERV (viral encepathalopathy and retinopathy) or also referred to as VNNV (viral nervous necrosis virus)
Loma	*Loma branchialis* (*syn. L. morhua*.)
OTHER	Any agent that produces a cytopathic effect in cell culture during inspection.

~~C. Non-reportable pathogens include: those which are not listed above and which are currently recognized to occur with regularity in the State of Maine.~~

3. Testing ~~requirements~~ Requirements for ~~Diseases~~ Pathogens of Regulatory Concern

	Marine Site and Hatchery-based Broodstock		Wild Caught Broodstock		Production Stock			
	Size Group 4		Size Group 4		Size Group 1		Size Groups 2 & 3	
Inspection Testing Requirement	Exotic	~~Reportable~~ Endemic/ Limited Distribution	Exotic	~~Reportable~~ Endemic/ Limited Distribution	Exotic	~~Reportable~~ Endemic/ Limited Distribution	Exotic	~~Reportable~~ Endemic/ Limited Distribution
Active Surveillance	VHSV IHNV ISAV-DEL La02β Other ~~CPE agents~~	BF IPNV Nodavirus Loma Histology for General Baseline	Biosecurity audits quarterly		VHSV IHNV ISAV-DEL	IPNV Nodavirus Other ~~CPE agents~~	VHSV IHNV ISAV-DEL La02β Other ~~CPE agents~~	BF IPNV Nodavirus Loma
Passive Surveillance	GID Other	ISAV-HPR0 Other	VHSV IHNV ISAV-DEL Other ~~CPE agents~~ GID La02β	Nodavirus IPNV ISAV-HPR0 BF Loma Other	La02β GID Other	BF ISAV-HPR0 Loma Other	GID Other	ISAV-HPR0 Other

4. Inspection Procedure: The following procedures shall be carried out by an inspector, as defined in these regulations.

   A. ~~A fish culture facility inspection of each production lot shall be completed at least annually~~. Qualified source/hatchery inspection: Except for approved quarantine facilities, those facilities which intend to serve as a qualified source/hatchery for import or transfer to other fish cultures facilities or that stock fish into the coastal waters of the State shall complete an inspection of each production lot at least annually. Lot inspections may occur at different times of the year, as long as all lots are tested at least once every twelve months. Inspection of a lot should occur within 4 months prior to a proposed transfer date.

      ~~(1)~~ When a lot of fish which has only had partial pathogen screening due to small size at the time of testing is to be moved from the premises, and the fish have attained a sufficient size to allow testing for a complete range of pathogens, then additional testing to complete an overall pathogen screening of a production lot before transfer should be completed.

   B. Fish health inspections shall be conducted at a time or times of the year conducive for the detection of pathogens and with regard to the age and size of fish and environmental conditions.

   C. A visual exam of all tanks/raceways to assess general health status shall be conducted during the annual inspection.

   D. Testing procedures for infectious agents shall be conducted according to requirements and methodologies approved by the Commissioner. Testing requirements for Gadids in the respective size groups shall be conducted according to Chapter 24.32(1)(C). For viral and bacterial pathogens, the inspector shall test at the 95% confidence level by isolation procedures, 5% prevalence per lot. For Nodavirus, a viral agent, the inspector shall test 10% of lethally sampled larvae or fish via RT-PCR. For Loma, general parasitology, and baseline

histology, the inspector shall test at the 95% confidence, 20% assumed prevalence level per lot.

E. Spawning Broodstock shall be tested within 30 days immediately before or after spawning for diseases of regulatory concern according to Chapter 24.32(1)(C).

(1) Reproductive fluids shall be sampled at the 100% level or lethal sampling at the 10% prevalence up to a maximum of 30 fish per lot and reproductive fluids at the 2% prevalence level. Reproductive fluids can be collected by trained facility personnel under the direction of the inspector using a specimen chain of custody form.

(2) If neither the lethal sampling option nor reproductive fluid sampling options are appropriate for a facility with limited, valuable broodstock, then to eliminate lethal sampling of brood, the facility must:

(a) Maintain the broodstock in a physically separated or isolated room or building from production lots with restricted entry and a documented biosecurity plan in place. The biosecurity plan and the facility must be available for veterinary review during inspections.

(b) Individually identify brood fish by means of a permanent tag or other marking device.

(c) For wild-caught broodstock, sample progeny as part of routine facility inspections. Results of this testing as well as the testing of a representative sample at the time of initial movement, as descried in Chapter 24.30(3)(A)(2), will be applied toward the broodstock health history.

(d) For hatchery-based ~~brood fish~~ broodstock, lethal sampling to continue testing history should come from other fish from the same lot of production fish not being used for brood.

(e) ~~For Marine site cultured selected brood fish~~ For broodstock selected from marine net-pen facilities, lethal sampling at the time the fish are introduced to a land based facility is required, including all testing as outlined for size group 2, and will include additional bacterial testing to include screening for *Francisella species*. Fish must be held in an approved quarantine facility for the first 6 weeks after introduction to the facility, and any mortalities must be tested as described for marine site broodstock above.

(3) Complete laboratory diagnostic testing (virology, bacteriology and parasitology) done on broodstock mortalities during a given year should be included for either lethal or non-lethal sampling options.

F. Sample size:

(1) For viral and bacterial pathogens the number of samples to be collected from a given lot shall be based upon stratified random sampling which provides 95 percent confidence of detecting a pathogen with an assumed minimum prevalence of detectable infection of two to twenty percent as follows:

Minimum sample sizes for populations varying from 50 to infinity are as follows:

Assumed Prevalence:	2%	5%	10%	20%
Population or lot size	Size	of	Sample	
50	50	35	20	5
100	75	45	23	8
250	110	50	25	11
500	130	55	26	13
1,000	140	55	27	14

1,500	140	55	27	14
2,000	145	60	27	15
10,000	145	60	27	15
100,000 and any larger	150	60	30	15

The above sample sizes are the minimum number of fish to be tested and in situations where pathogens are suspected, additional samples shall be taken at the discretion of the fish health inspector. The method of collecting sub samples from rearing units to obtain a representative sample is left to the discretion of the inspector.

(2) Inspections shall be performed and samples collected by the inspector or a person working under his/her supervision. The inspector is responsible for all work performed.

(3) Pathogens as described in Chapter 24.32(3) detected by passive surveillance between annual fish health inspections must be reported by the marine fish culture facility owner to the Commissioner at the time of inspection.

(4) Upon completion of the annual inspection of the fish culture facility, an inspection report will be issued to the marine fish culture facility owner or operator and the Commissioner. Upon receipt of the inspection report, the Department will review the report and may issue a transfer permit if the report meets the standards outlined in these rules.

(5) Lots of ~~fish and/or gametes~~ finfish transferred from qualified sources/hatcheries to a receiving facility will not invalidate the receiving fish culture facility's annual inspection status.

(6) Lots of ~~fish and/or gametes~~ finfish received from sources other than qualified sources/hatcheries that do not comply with Chapter 24.30(3)(A) will invalidate the receiving fish culture facility's annual inspection status.

24.34 Pleuronectids (fish in the family ~~pleuronectidae~~ Pleuronectidae)

1. Definitions

For the purposes of these rules the following terms have the following meanings:

A. "Size Groups" means:
"Size Group 1": Larval period and juvenile size range of ≤ 4 cm in length.
"Size Group 2": Juvenile ≥ 4 cm in length and yearlings.
"Size Group 3": Production fish greater than one year old.
"Size Group 4": Mature fish or fish set aside to be used as broodstock upon maturity.

2. Pathogen list for ~~Halibut~~ Pleuronectids

A. Exotic pathogens include:

IHNV	Infectious Hematopoietic Necrosis Virus
VHSV	Viral Hemorrhagic Septicemia Virus
ISAV-DEL	Infectious Salmon Anemia Virus (HPR-deleted variants)
GID	*Francisella species* – granulomatous inflammatory disease
La02β	*Listonella (Vibrio) anguillarum* serotype 02 beta
OTHER	Any ~~pathogen~~ agent not detected in Maine as of the effective date of these rules that produces a cytopathic effect in cell culture during inspection.

B. ~~Reportable~~ Endemic/Limited Distribution pathogens include:

IPNV	Infectious Pancreatic Necrosis Virus
ISAV-HPR0	Infectious Salmon Anemia Virus (non-deleted variants)
BF	Furunculosis (*Aeromonas salmonicida*) typical and atypical
Nodavirus:	VERV (viral encepathalopathy and retinopathy) or also referred to as VNNV (viral nervous necrosis virus)

Loma *Loma branchialis* (*syn. L. morhua*.)
OTHER Any agent that produces a cytopathic effect in cell culture during inspection.

~~C. Non-reportable pathogens include:~~
~~Those which are not listed above and which are currently recognized to occur with regularity in the State of Maine.~~

3. Testing ~~requirements~~ Requirements for ~~Diseases~~ Pathogens of Regulatory Concern

	Marine Site and Hatchery-based Broodstock		Wild Caught Broodstock		Production Stock			
	Size Group 4		Size Group 4		Size Group 1		Size Groups 2 & 3	
Inspection Testing Requirement	Exotic	~~Reportable~~ Endemic/Limited Distribution	Exotic	~~Reportable~~ Endemic/Limited Distribution	Exotic	~~Reportable~~ Endemic/Limited Distribution	Exotic	~~Reportable~~ Endemic/Limited Distribution
Active Surveillance	VHSV IHNV ISAV-DEL La02β Other ~~CPE agents~~	BF IPNV Nodavirus Loma General Parasitology Histology for general baseline	Biosecurity audits quarterly		VHSV IHNV ISAV-DEL	IPNV Nodavirus Other ~~CPE agents~~	VHSV IHNV ISAV-DEL La02β Other ~~CPE agents~~	BF IPNV Nodavirus Loma General Parasitology Histology for general baseline
Passive Surveillance	GID Other	ISAV-HPR0 Other	VHSV IHNV ISAV-DEL La02β Other ~~CPE agents~~ GID	Nodavirus IPNV ISAV-HPR0 BF Loma Other	La02β GID Other	BF ISAV-HPR0 Loma Other	GID Other	ISAV-HPR0 Other

4. Inspection Procedure: The following procedures shall be carried out by an inspector, as defined in these regulations.

A. ~~A fish culture facility inspection of each production lot shall be completed at least annually.~~ Qualified source/hatchery inspection: Except for approved quarantine facilities, those facilities which intend to serve as a qualified source/hatchery for import or transfer to other fish culture facilities or that stock fish into the coastal waters of the State shall complete an inspection of each production lot at least annually. Lot inspections may occur at different times of the year, as long as all lots are tested at least once every twelve months. Inspection of a lot should occur within 4 months prior to a proposed transfer date.

~~(1)~~ When a lot of fish which has only had partial pathogen screening due to small size at the time of testing is to be moved from the premises, and the fish have attained a sufficient size to allow testing for a complete range of pathogens, then additional testing to complete an overall pathogen screening of a production lot before transfer should be completed.

B. Fish health inspections shall be conducted at a time or times of the year conducive for the detection of pathogens and with regard to the age and size of fish and environmental conditions.

C. A visual exam of all tanks/raceways to assess general health status shall be conducted during the annual inspection.

D. Testing procedures for infectious agents shall be conducted according to requirements and methodologies approved by the Commissioner. Testing requirements for ~~Halibut~~ Pleuronectids in the respective size groups shall be conducted according to Chapter 24.34(3). For viral and bacterial pathogens, the inspector shall test at the 95% confidence level, 5% prevalence per lot by isolation procedures. For Nodavirus, a viral agent, the inspector shall additionally test 10% of lethally sampled larvae or fish via RT-PCR. For Loma, general parasitology, and baseline histology, the inspector shall test at the 95% confidence, 20% assumed prevalence level per lot.

E. Spawning Broodstock shall be tested within 30 days immediately before or after spawning for diseases of regulatory concern according to Chapter 24.34(3).

(1) Reproductive fluids shall be sampled at the 100% level or lethal sampling at the 10% prevalence up to a maximum of 30 fish and reproductive fluids at the 2% prevalence level. Reproductive fluids can be collected by trained facility personnel under the direction of the inspector using a specimen chain of custody form.

(2) If neither the lethal sampling option nor reproductive fluid sampling options are appropriate for a facility with limited, valuable broodstock, then to eliminate lethal sampling of brood, the facility must:

(a) Maintain the broodstock in a physically separated or isolated room or building from production lots with restricted entry and a documented biosecurity plan in place.

(b) Individually identify brood fish by means of a permanent tag or other marking device.

(c) For wild-caught broodstock, sample progeny as part of routine facility inspections. Results of this testing as well as the testing of a representative sample at the time of initial movement, as descried in Chapter 24.30(3)(A)(2), will be applied toward the broodstock health history.

(d) For hatchery-based ~~brood fish~~ broodstock, lethal sampling to continue testing history should come from other fish from the same lot not being used for broodstock.

(e) ~~For Marine site~~ For marine net-pen facility cultured ~~brood fish~~ broodstock, lethal sampling at the time the fish are introduced to a land based facility is required, including all testing as outlined for size group 2, and will include additional bacterial testing to include screening for *Francisella species*. Fish must be held in an approved quarantine facility for the first 6 weeks after introduction to the facility, and any mortalities must be tested as described for marine site broodstock above.

(3) Complete laboratory diagnostic testing (virology, bacteriology and parasitology) done on broodstock mortalities during a given year should be included for either lethal or non-lethal sampling options.

(F) Sample size:

(1) For viral and bacterial pathogens the number of samples to be collected from a given lot shall be based upon stratified random sampling which provides 95 percent confidence of detecting a pathogen with an assumed minimum prevalence of detectable infection of two to twenty percent as follows:

Minimum sample sizes for populations varying from 50 to infinity are as follows:

Assumed Prevalence:	2%	5%	10%	20%

Population or lot size	Size	of	Sample	
50	50	35	20	5
100	75	45	23	8
250	110	50	25	11
500	130	55	26	13
1,000	140	55	27	14
1,500	140	55	27	14
2,000	145	60	27	15
10,000	145	60	27	15
100,000 and any larger	150	60	30	15

The above sample sizes are the minimum number of fish to be tested and in situations where pathogens are suspected, additional samples shall be taken at the discretion of the fish health inspector. The method of collecting sub samples from rearing units to obtain a representative sample is left to the discretion of the inspector.

(2) Inspections shall be performed and samples collected by the inspector or a person working under his/her supervision. The inspector is responsible for all work performed.

(3) Pathogens as described in Chapter 24.34(3) detected by passive surveillance between annual fish health inspections must be reported by the marine fish culture facility owner to the Commissioner at the time of inspection.

(4) Upon completion of the annual inspection of the fish culture facility, an inspection report will be issued to the marine fish culture facility owner or operator and the Commissioner. Upon receipt of the inspection report, the Department will review the report and may issue a transfer permit if the report meets the standards outlined in these rules.

(5) Lots of ~~fish and/or gametes~~ finfish transferred from qualified sources/hatcheries to a receiving facility will not invalidate the receiving fish culture facility's annual inspection status.

(6) Lots of ~~fish and/or gametes~~ finfish received from sources other than qualified sources/hatcheries that do not comply with Chapter 24.30(3)(A) will invalidate the receiving fish culture facility's annual inspection status.

APPENDIX A
(Molluscan bivalves)

Key: B = Benign; U = Unknown; PD = Potentially Dangerous; D = Dangerous; P = Pest

Status of Seriousness	Diseases	Geographic Zones	States
	AMERICAN OYSTERS (*C. virginica*)		
(U)B	Viral gametocyte hypertrophy	Entire East & Gulf Coasts	
D	Herpesvirus (hemocytic)	CGM	ME
B	Chlamydia-Rickettsia Disease	Entire east coast	
B	(in ducts and stomach)	Entire east coast	
B	(in tubules)	Entire east coast	
(U)PD	Actinomycosis	CSN, DB	NY, NJ
D	*Perkinsus marinus*	DB, CB, PS (Entire	NJ, DE, MD,
	Estuaries east & Gulf Coast)	VA, NC	
D	Haplosporidium nelsoni (MSX)	CSN, DB, DE, CMA	NJ, NY, DE,
		CGM*	MD, VA, ME
		Marsh River, ME	*Wellfleet, MA
D	*Minchinia costalis* (SSO)	CGM, CSN, CMA	High salinity estuaries of entire northeast
B	*Nematopsis ostrearum*	All Atlantic & Gulf coasts	
B	*Ancistrocoma*-like ciliates	All Atlantic & Gulf coasts	
B	*Sphenophrya*-like ciliates	All Atlantic & Gulf coasts	
B	*Hexamita* sp.	All Atlantic & Gulf coasts	
(U)P	Turbellaria	CSM, CGM	NY, MA, ME
P	*Bucephalus cuculus*	CB, DB, PS, CMA	All but ME
		CSM, CGM?	
P	Nematode infections	CB, PM, DB	
PD	Malignant neoplasia	All east coast	
P	Gill Turbellarian	CGM	Canada
D	Malpeque Bay disease		Canada (Gulf of St. Lawrence)
	SOFT-SHELL CLAMS (*Mya arenaria*)		
D	Viral hematopoietic neoplasia	CGM, CSN	
B	Chlamydia	All Northeast	
PD	*Perkinsus* sp.	CB, CSN	MD, RI
B		Ciliates	All Northeast
U	*Pseudoklossia* kidney gregarine	CSN, CGM	
P	*Bucephalus* sp.	Unknown	
U	Gill dysplasia	Entire coast	
PD	Gonadal neoplasia	CGM	Searsport, ME
			Dennysville, ME
	HARD-SHELLED CLAMS (*Mercanaria mercenaria*)		
B	Chlamydia	Entire northeast	
P	Trematode	CSN	NJ
B	Ciliates	Entire range	
U	Arrested gametogenesis	CSN	RI
PD	Chitried fungus	Eastern Canada	
	BAY SCALLOPS (*Aequipecten irradians*)		
PD	Microsporidan	GMA	MA
U	Kidney gregarine (*pseudoklossia*)	CSN	MA, CT

*Accidental introduction in Wellfleet, MA.

Appendix (Cont.)

Status of Seriousness	Diseases	Geographic Zones	States
	BLUE MUSSELS (*Mytilus edulis*)		
B	Chlamydia	Entire coast	
U	Bacterial disease of plycate organ	CMA, CNS	
PD	Haplosporidan	CGM	ME
U	*Pseudoklossia* sp. in kidney	CSN, CGM	MA, ME
B	*Steinhusia* in ova	CSN	RI
B	Ciliates	Entire range	
P	Trematode redia	CGM, CSN, CMA	
P	Trematode metacercariae *Gymnophallus bursicola*	CGM, CSM, CMA	
P	Copepod	CGM	ME
P	*Pinnotheres maculatus*	CSN, CGM	ME
PD	*Mytilicola intestinalis*	Europe	
U	Haematopoietic neoplasm	UK	
D	*Mytilicola orientalis*	US West coast	
	SEA SCALLOPS *(Placopecten magellanicus)*		
PD	Abscesses	CGM	ME
U	Fungus		ME (Sheepscot River)
	EUROPEAN OYSTERS (*Ostrea edulis*)		
D	*Mytilicola orientalis*	West coast of US, France	
U	Haematopoietic neoplasm	France	
D	Shell disease (fungus)	European Atlantic coast Canada (Maritime provinces)	
D	*Minchinia armoricana*	France, Netherlands	
D	*Martiella refringens*	France	
D	Rickettsia	France	
D	*Bonamia ostreae*	France, Denmark, Netherlands	
PD	Herpes-like virus	Wales, GB	
D	Microcell disease	California, Connecticut	

APPENDIX B
(Finfish)

Quick Reference Disease and Pathogen Table

Abbreviation	Pathogen	Disease	Gadids	Halibut	Salmonids	Last Updated
BF	Aeromonas salmonicida	Furunculosis	Reportable	Reportable	Reportable	2009
BKD	Renibacterium salmoninarium	Bacterial Kidney Disease	N/A	N/A	Reportable	2009
BR	Yersinia ruckeri	Enteric Redmouth	N/A	N/A	Reportable	2009
CS	Ceratomyxa shasta	Ceratomyxosis	N/A	N/A	Exotic	2009
GID	Francisella species	Granulomatous inflammatory disease	Exotic	Exotic	N/A	2009
IHNV	Infectious Hematopoietic Necrosis Virus	Infectious Hematopoietic Necrosis (IHN)	Exotic	Exotic	Exotic	2009
IPNV	Infectious pancreatic necrosis virus	Infectious pancreatic necrosis virus	Reportable	Reportable	Reportable	2009
ISAV	Infectious salmon anemia virus	Infectious Salmon Anemia (ISA)	Exotic	Exotic	Exotic	2009
La02ß	Listonella (Vibrio) anguillarum serotype 02 ß	Vibriosis	Exotic	Exotic	Exotic	2009
Loma	Loma branchialis (syn. L. morhua.)	Loma	Reportable	Reportable	Non-reportable	2009
Nodavirus	Nodavirus or also referred to as VNNV (viral nervous necrosis virus)	VERV (viral encepathalopathy and retinopathy virus) or also referred to as VNNV (viral nervous necrosis virus)	Reportable	Reportable	N/A	2009
OMV	Oncorhyncus masou virus	Onchorhyncus masou (Herpesvirus salmonis)	N/A	N/A	Exotic	2009
PKD	PKX unclassified myxozoan	Proliferative kidney disease	N/A	N/A	Exotic	2009
SPDV	Salmonid pancreatic disease virus	Salmonid pancreatic disease	N/A	N/A	Exotic	2009
VHSV	Viral hemorrhagic septicemia virus	Viral hemorrhagic septicemia	Exotic	Exotic	Exotic	2009
WD	Myxobolus cerebralis	Whirling disease	N/A	N/A	Exotic	2009

Basis Statement

This rule amends Chapter 24 to make clarifying changes, including improving and creating definitions as necessary, using consistent terminology, and providing updates throughout the chapter. The rule also allows the Commissioner, in consultation with the Aquatic Animal Health Technical Committee, to issue permits to an approved quarantine facility from facilities that do not otherwise meet the regulation requirements, under certain limited circumstances. Transfer from an approved quarantine facility is permitted only if post-import testing provides satisfactory evidence of freedom from pathogens of regulatory concern for which evidence of disease freedom of the import was not satisfied at the time of import. The rule allows for consideration of evidence other than direct testing of lots to provide evidence of disease freedom from Ceratomyxosis, Whirling disease, and PKD if importation is only in the form of embryos that have been iodine disinfected before and immediately after import, prior to the time of introduction to the waters of the receiving facility.

Based on comments received the Department has made the following changes to the adopted rule:

1. The Department modified the definition for a "quarantine facility" to an "approved quarantine facility" to reflect that the exemptions created by this rule require an applicant to meet certain criteria to obtain approval to import fish from facilities that do not otherwise meet the regulation's requirements. The Department also changed all references to quarantine facility to "approved quarantine facility" to be consistent with the change to the definition.

2. The Department has also made some additional changes to clarify language in response to comments provided, but these changes do not substantively change the intent or impact of the original proposed rulemaking.

3. In 24.34 (3), the Department added ISAV_HPR0, which had been added to the other tables of pathogens of regulatory concern but inadvertently left off this table. More specifically, ISAV-DEL was included, but ISAV_HPR0 was not added to the passive surveillance table as it was for the salmonid and gadid tables. This table always required surveillance for ISAV; the intent of this change is the same as it is in other sections where the Department is separating out the non-pathogenic HPR0 into a lesser category.

Summary of Comments
Notice of this proposed rulemaking appeared on April 25, 2018 in the five major daily newspapers as published by the Secretary of State. On April 25, 2018, the rule was posted on the DMR website, and electronic messages were sent to individuals who subscribe to DMR notices, and members of the Aquatic Animal Health Technical Committee. The public hearing was advertised in compliance with the procedures outlined in the Maine Administrative Procedures Act and was held on May 16, 2018 at 2:30pm in the DMR conference room, Augusta. The comment period closed on May 29, 2018.

Public Hearing
May 16, 2018
2:30pm
DMR-Augusta office
Conference Room 118

Attendance:

Name	**Affiliation (If specified)**
Jennifer Fortier	None listed
Michele Walsh	ME DACF
Brian Rayback	Pierce Atwood
Bill Keleher	Kennebec Biosciences
Ben Willaler	Whole Oceans
Nick King	Fishvet Group
Jason Collins	Fishvet Group
Meredith Mendelson, Deirdre Gilbert, Marcy Nelson, and Amanda Ellis	DMR Staff

Hearing Comments Summary:

Opposed	**Neutral**	**Support**
0	0	2

Comments in Support:

Bill Keleher, President/CEO of Kennebec River Biosciences:
My name is Bill Keleher and I am President/CEO of Kennebec River Biosciences an aquatic animal health and biotechnology company located in Richmond, ME. Our company conducts regulatory inspections and diagnostic testing for the commercial aquaculture industry, state & federal resource agencies, and academic & research institutions. I am an American Fisheries Society — Fish Health Section Fish Health Inspector and Fisheries & Ocean Canada Fish Health Official.

I believe the changes proposed to DMR's Chapter 24 regulations are consistent with the overall goal of protecting state resources while allowing for the development of land-based aquaculture within the state. These are a few comments I would like to make regarding the proposed changes.

Comment 1. Non-Vertically Transmitted Pathogens

The proposed language included in section 24.21 (1) (C) (3) exempting freedom for Ceratomyxa shasta, Myxobolus cerebralis, and Tetracapsuloides bryosalmonae based on the import of embryos that have been disinfected.

The inclusion of this language is a prudent step given that none of the listed pathogens are capable of being vertically transmitted via the egg and standard iodophore disinfection will eliminate any surface associated agents in the extremely rare chance these agents would be present. Given that Chapter 24 compliant pathogen testing will occur post-hatch while under quarantine, the ability to exempt testing for these agents will allow testing to occur sooner. The end result is that animals can be released from quarantine in an expedited manner.

Comment 2. Infection Salmon Anemia Virus (ISAV) Strains

The proposed language included in the definitions section includes new definitions for "HPRO ISAV" and "HPR-deleted ISAV".

The inclusion of this language is warranted and supported by both peer reviewed science and World Organization of Animal Health information. The testing methodologies, management, and regulatory response to these two strains of ISAV are different. While HPR-deleted ISAV strains are pathogenic, HPRO strains have not been shown to cause clinical disease or mortality in infected fish. Previous language only referred to ISAV as a single virus and which presented issues when it comes to detection and the regulatory response.

In closing, I support the Departments changes to Chapter 24 in their effort to facilitate the import of aquatic species (fish and eggs) that do not meet full compliance with current regulations. These changes will allow land-based recirculating aquaculture systems (RAS) to obtain the necessary seed stock for their operations that they would otherwise not be able to obtain in North America based on their production schedules. On one final note, it should be stressed that most other countries use pathogen surveillance programs that operate at a very high level generally following World Organization of Animal Health (OIE) standards. These OIE standards have significant deviations from Chapter 24 including pathogen freedom language that is not envisioned by Chapter 24. The proposed language will give the Commissioner discreation to recognize these differences and facilitate movements in support of the emerging land-based aquaculture sector here in Maine.

Brian Rayback, Peirce Atwood LLP, (on behalf of Whole Oceans):
Thank-you. Good afternoon. My name is Brian Rayback and I am a lawyer with Peirce Atwood. I am here representing Whole Oceans LLC today. As you may know, Whole Oceans is developing a recirculating aquaculture system at a land based facility in Bucksport. To supply the facility with adequate supplies of eggs, Whole Oceans needs to import Atlantic salmon eggs. Whole Oceans is planning to import their eggs to a quarantine facility for post-import testing for pathogens of regulatory concern that were not tested for prior to import. We support and are very appreciative of the Department's efforts to amend chapter 24. I would like to offer today some suggestions for minor revision to ensure the amendments accomplish what I think are your goals. I plan just to highlight our suggestions as my partner Andrea Maker has already provided a detailed set of written comments. I am also going to limit myself to legal issues, we'll leave technical and scientific issues to the experts.

The first point I want to start with is, we ask you consider small changes to the new provision that would allow DMR to authorize imports that don't yet meet all the provisions of Chapter 24 provided that they go to a quarantine facility for post import testing. This is in 24.21 (1) (A) (1), as drafted this proposal starts in the first paragraph with a prohibition on importing any salmonid finfish that don't

meet provisions of chapter 24 and then in the second paragraph there is a provision that arguably contracts that, which says the commissioner may authorize it some cases. To eliminate any potential confusion, we suggest adding some language along the lines of "except as provided in this subsection" to the beginning of that first paragraph that will make clear that the two paragraphs are working together and there is no way to read it down the line and contend that they are in conflict.

You may also want to do the same thing in two other spots, 24.30 (1) (A) and 24.30 (3) (C), which deal with a similar exception under the marine fish health inspection provisions. The details of those are included in our written comments, so I won't dwell on that.

The second point, in the same 24.21 (1) (A) provision, where we started-we proposed some minor revisions that we think help clarify some of the language and the intent. Primarily this would be to replace the end of the sentence with language that you see in our comments. Basically, the current proposal reads: "which evidence of disease freedom of the import was not satisfied." We proposed "which evidence of freedom was not certified at the time of import." Just trying to make that read more smoothly. We are also suggesting the word "approved" be added before the phrase quarantine facility in the second sentence, so it would read: "transfer from an approved quarantine facility," etc. and you go from there.

Now that ties into another comment that I'd like to mention, which is that we suggest adding a new definition for what exactly is an approved quarantine facility at 24.10 of the rule. We recognize that the definition of quarantine facility already includes the language that it must be an approved facility, but it is not clear yet what types of facilities may be approved. We are suggesting that you consider adding another definition that specifies an approved quarantine facility is one that the: "*Commissioner has determined is designed, built and operated in a manner that adequately prevents the introduction of pathogens of regulatory concern into waters outside the quarantine facility."* That will help, we think, make clear to the public and the regulated community that when the Commissioner does approve such a facility why he or she is doing so.

Finally, I just wanted to highlight a couple of clarifications to the materials an applicant has to include in an application when seeking a license. First, we would propose removing the proposed language at 24.05 (8), which says that the "Commissioner may exempt certain imports into approved quarantine facilities." That authority is already adequately laid out elsewhere. That's the provision we were just talking about and it doesn't really fit into a list of what the applicant must provide in an application to obtain a license. We do think, however, that it would be a good place here to instead specify what materials an applicant must provide to DMR about the quarantine facility and about the post import testing protocols that will be in place. That will ensure that the Commissioner has the information that he or she needs to make these decisions. Our specific language for that is in our comments. Again, just trying to hit the high points, so I won't dwell on that.

Second, we would also recommend some small changes to the language in 24.05 (9) which requires the applicant to provide a fish health inspection report under the Northeast Fish Health Committee guidelines. We're suggesting that the new language as applicable to these rules should apply not to Chapter 24, but rather to the NFHC guidelines themselves. We think that's what is intended, because only some of those guidelines would be applicable to the egg import issue that we are dealing with here. Our suggested language is in our comments.

Opposed	Neutral	Support
1	0	1

Andrea C. Maker, Peirce Atwood LLP, submitted via email, May 14, 2018.
The Maine Department of Marine Resources ("DMR") is proposing changes to DMR Rule Chapter 24, Importation of Live Marine Organisms ("Chapter 24") to accommodate the importation of eggs from facilities that do not meet all Chapter 24 requirements until the eggs meet the remaining tests at the end of a quarantine process. More specifically, the proposed changes would authorize the Commissioner of DMR, in consultation with the Aquatic Animal Health Technical Committee, to issue permits to allow the importation of eggs from facilities that do not meet all Chapter 24 requirements to approved quarantine facilities. The changes also propose to distinguish fish culture facilities between net-pen and land-based aquaculture facilities for purposes of applying various sections of Chapter 24 to the appropriate type of fish culture facility.

These comments to the proposed changes to Chapter 24 published, on April 25, 2018, are submitted on behalf of Whole Oceans LLC ("Whole Oceans"). Whole Oceans is developing a recirculating aquaculture system in a land-based aquaculture facility in Bucksport, Maine to grow Atlantic salmon from egg to full grow-out, and to harvest the fish for market from the land-based aquaculture facility. To supply the facility with adequate supplies of eggs, Whole Oceans needs to import Altantic salmon eggs. Whole Oceans is planning to import their eggs to a quarantine facility for post-import testing for pathogens of regulatory concern that were not tested for prior to import. Whole Oceans will engage state-of-the-art-technology and detailed operating procedures that will ensure that the eggs imported into, and the effluent discharged from, the quarantine facility are free from pathogens of regulatory concern as defined in Chapter 24 before being released from the quarantine facility. As the first such facility in Maine, Whole Oceans will proudly set quarantine facility standards of design and operation that will guide regulations and industry practices to protect the health and sustainability of the fish grown in its facility, and as importantly, to protect indigenous marine life and its environment. Maine stands to position itself as a national and international leader in land-based aquaculture and Whole Oceans intends to partner with Maine in that effort.

In general, Whole Oceans supports the proposed changes to Chapter 24 and appreciates DMR's efforts to develop a regulatory scheme that will advance land-based aquaculture in Maine.
These comments propose language changes to ensure clear definitions, clear authority of the Commissioner and consistent legal language to result in the intentions underlying the proposed changes. These comments respectfully recommend five substantive language changes for DMR consideration. For your convenience, our suggested language changes are presented in *italics*.

Comment 1. Incorporate the Exception into the Prohibited Activity Language to Ensure Legal Consistency between the Prohibition and the Exception

The current proposed language for Section 24.21 (1) (A) (1) states:

"It is unlawful to transfer live salmonid gametes or finfish to any fish culture facility in Maine or stock salmonid finfish *or* gametes into the coastal waters of Maine that do not meet the requirements of these rules**."**

The proposed change then adds a second paragraph that provides an exception to this prohibition, giving the Commissioner authority to issue a permit to import or transfer such fish to an approved

quarantine facility even when they do not meet the requirements of these rules. As proposed, the two sentences contradict one another. (There is a third sentence being proposed to this section, which we address in Comment 2 below). We recommend referencing and incorporating the exception into the prohibition statement, as follows:

Proposed language for Section 24.21 (1) (A) (1): *Except as provided in this subsection*, it is unlawful to transfer salmonid finfish to any fish culture facility in Maine or stock salmonid finfish into the coastal waters of Maine that do not meet the requirements of these rules.

The Commissioner may, at his discretion and in consultation with the AAHTC, issue a permit to import or transfer finfish from sources or facilities that do not meet the requirements of these rules to an approved quarantine facility…

Adopting this "*Except as provided in this subsection*" language in sentence one will render the two sentences legally consistent.

Likewise and for the same reason, the first sentence of Section 24.21 (1) (C) (3) should also incorporate this exception language.

Proposed language for Section 24.21 (C) (3): *Except as provided in section 24.21 (1) (A) (1),* any person applying for a permit to import salmonid finfish into the State of Maine shall demonstrate that the finfish being imported are free from evidence of all pathogens of regulatory concern; and that the finfish are from a qualified source/hatchery.

This same comment and proposed language are recommended for the parallel language related to the prohibition of transferring live marine finfish in Sections 24.30 (1) (A) and 24.30 (3) (C).

Comment 2. Satisfying Evidence of Freedom from Remaining Pathogens of Regulatory Concern

The second sentence in the second paragraph of the proposed new language for Section 24.21 (1) provides the circumstances that allow transfer of the finfish from an "approved quarantine facility". The sentence may be more clearly stated as follows:

Current Proposed Language for the second sentence in the second paragraph of Section 24.21 (A) (1): Transfer from a quarantine facility, or a change in operation to that which is less biosecure, may be permitted if post-import testing provides satisfactory evidence of freedom from those pathogens of regulatory concern for which evidence of disease freedom of the import was not satisfied.

Suggested Language for this sentence in Section 24.21 (A) (1)*: "Transfer from an approved quarantine facility, or a change in operation to that which is less biosecure, may be permitted if post-import testing provides satisfactory evidence of freedom from those pathogens of regulatory concern for which evidence of freedom was not certified at the time of import."*

Comment 3. Definition of "approved quarantine facility."

The operative language that addresses the new Commissioner authority is found in the first sentence of the second paragraph in Section 24.21 (1):

Current Proposed Language: The Commissioner may, at his discretion and in consultation with the AAHTC, issue a permit to import or transfer finfish from sources or facilities that do not meet the requirements of these rules to an approved quarantine facility.

This operative language is contingent on an "approved quarantine facility."

Section 24.01 (27) provides the definition of a "Quarantine facility". Given the fundamental importance of the term "approved quarantine facility", we propose that a new definition be added for an "*approved quarantine facility*." We also propose to strike the word "approved" from within the definition of "quarantine facility" to clarify the difference between the two. Also, our interpretation is that the use of the phrases "prevent pathogen introduction" and the "spread of disease" is unnecessarily redundant, and we propose striking the reference to "the spread of disease".

Current Proposed Language for Section 24.10 (27): "Quarantine facility" means an approved facility in which organisms are raised or held in isolation to prevent pathogen introduction or the spread of disease.

Suggested Language for Section 24.10 (27): *"Quarantine facility" means a facility in which organisms are raised or held in isolation to prevent the introduction of pathogens of regulatory concern into waters outside the facility.*

We suggest the addition of a new definition for "*Approved quarantine facility*" as follows:

Suggested Language for Section 24.10 *(XX):* *"Approved quarantine facility" means a quarantine facility which the Commissioner has determined is designed, built and operated in a manner that adequately prevents the introduction of pathogens of regulatory concern into waters outside the quarantine facility.*

In the alternative, the language describing an approved quarantine facility could be added to the operative language in 24.21 (1) (A) (1), *"...to a quarantine facility that has been determined by the commissioner to adequately prevent the introduction of pathogens of regulatory concern into waters outside the quarantine facility."* This alternative is less appealing because the language would need to be added to all the sections where a reference to an approved quarantine facility is currently provided.

We note that the reference to an approved quarantine facility is also found in numerous sections throughout Chapter 24. A review of those sections indicates that Chapter 24 would similarly benefit by a definition of "approved quarantine facility."

Comment 4. Permit Application for Marine Organisms – Add a Requirement for a Description of the Quarantine Facility

Section 24.05 outlines information that an applicant must provide when seeking a permit for importation. Subsection (8) requires that the application for an egg import permit provide a statement of examination by an approved aquatic pathogen detection facility certifying that the marine organisms meet the requirements of Chapter 24. Then a new sentence is being proposed stating that:

Current Proposed Language: "The Commissioner may, in consultation with the AAHTC, exempt imports into approved quarantine facilities from this requirement."

We suggest that this language is misplaced in the Chapter. It is not necessary to cite the Commissioner's authority to exempt full compliance with the Chapter 24 requirements at the time of import in this particular section of Chapter 24, which outlines the information required on an application for import or introduction of marine organisms. Rather, this is an appropriate section to require the applicant to provide information describing the "quarantine facility" and post-import testing protocols that will allow the Commissioner to determine whether a quarantine facility will adequately prevent the introduction of pathogens of regulatory concern into waters outside the "quarantine facility". This information will help the Commissioner to determine whether a "quarantine facility" qualifies as an "approved quarantine facility." Accordingly, we suggest the following language replace the underlined language above:

Suggested Language: *"In the alternative, if the marine organisms to be imported or introduced are not certified to be free of one or more pathogens of regulatory concern, the applicant must provide a description of the quarantine facility and post-import testing protocols to be conducted to allow the Commissioner to determine whether or not the quarantine facility will adequately prevent the introduction of pathogens of regulatory concern into waters outside the quarantine facility."*

Comment 5. Permit Application for Marine Organisms – Clarify Applicability of Northeast Fish Health Committee Guidelines

Section 24.05 (9) requires an applicant to provide a fish health inspection report provided by the Northeast Fish Health Committee Guidelines ("NFHC Guidelines"). The proposed new language for Section 24.05 (9) adds the phrase "as applicable to these rules," to the beginning of the first sentence in this section.

Current Proposed Language for Section 24.05 (9): "as applicable to these rules, a valid fish health inspection report issued by a fish health inspector in accordance with the New England Northeast Fish Health Committee Guidelines and particularly the Guidelines for Importation.

We propose that the applicability should be directed not to Chapter 24, but rather to the sections of the NFHC Guidelines that apply to egg imports under Chapter 24. We therefore suggest the following language:

Suggested Language for Section 24.05 (9): "*a valid fish inspection report issued by a fish health inspector which meets the requirements of this Chapter and which meets any applicable Northeast Fish Health Committee Guidelines.*

Conclusion

On behalf of Whole Oceans and the future of sustainable, healthy land-based aquaculture in Maine, we thank the DMR and others for their diligence in designing a regulatory process that will protect indigenous marine life and its environment, while allowing Maine to engage it's unique and bountiful natural resources and dedicated human resources in the forefront of a burgeoning industry of land-based aquaculture.

DMR Response:

The Department appreciates the specific recommendations for language changes provided by Whole Oceans in both oral testimony at the public hearing and in writing. The Department also agrees that these changes will improve clarity in the rule, and has accepted these proposed changes with some minor adjustments. In particular, in response to Comment 4, the definition of "quarantine facility" was modified to "approved quarantine facility," and all references to "quarantine facility" were changed to reference "approved quarantine facility."

Sebastian Belle, Executive Director, Maine Aquaculture Association, submitted via email May 29, 2018

As per the Department's request the Maine Aquaculture Association (MAA) would like to offer the following comments on the Agency Rule-making Proposal on Chapter 24; Importation of Live Marine Organisms.

The Maine Aquaculture Association Opposes the proposed rule changes for two reasons.

1. No consultation occurred with the existing aquaculture industry prior to the draft rule being issued. The proposed rule changes are significant and could theoretically significantly increase the risk of introduction of new and exotic pathogens into the state.
2. The Commissioner's own expert technical panel, The Aquatic Animal Health Technical Committee, was not asked to review the proposed rule changes prior to the draft rule being issued.

MAA understands it is the departments intent to modify the existing chapter 24 rules in order to support the continued development of the aquaculture sector while protecting maines public resources. MAA has members that may benefit from some of the proposed changes. MAA is however extremely concerned at what appears to be a hurried with limited stakeholder input and even more limited technical review. MAA would respectfully suggest the department withdraw the proposed rule changes and as MAA has been suggesting for some time, convene a technical committee that includes experts and stakeholders to systematically review chapter 24 for any needed revisions. MAA is convinced that process can be done expeditiously and will result in revisions that are scientifically based and representative of all stakeholders concerns and knowledge. MAA stands ready to assist in such an effort.

DMR Response:

This proposed rule was drafted in response to a burgeoning industry, as the commenter notes. The Department's intent was to provide transparent, uniformly-applicable evaluation criteria to any applicant who would be soliciting the Department for an exemption to existing regulations, which previously would have been available only under the Special License process. The rulemaking process is an appropriate procedure by which to obtain public input from stakeholders, including the expert technical advice of the Aquatic Animal Health Technical Committee members, should they wish to provide comment on the process. Furthermore, these exemptions may not be granted without the input of the Aquatic Animal Health Technical Committee. The Department does not believe these proposed rules significantly increase the risk of introduction of new and exotic pathogens to the state. The Department understands that there are systematic changes needed to Chapter 24, and intends to engage a workgroup of key stakeholders to participate in that process in the near future.

Rule-Making Fact Sheet

(5 M.R.S., §8057-A)

AGENCY: 13-188- Department of Marine Resources

NAME, ADDRESS, PHONE NUMBER OF AGENCY CONTACT PERSON:
Amanda Ellis, Department of Marine Resources, 21 State House Station, Augusta, Maine 04333-0021 Telephone: (207) 624-6573; web address: http://www.maine.gov/dmr/rulemaking/

CHAPTER NUMBER AND RULE: Chapter 24 Importation of Live Marine Organisms Proposed Rule-making

STATUTORY AUTHORITY: 12 M.R.S. § 6071

DATE AND PLACE OF PUBLIC HEARING(S): May 16, 2018 at 2:30 p.m.: DMR Conference Room, Marquardt Building, 32 Blossom Lane, Augusta.

COMMENT DEADLINE: May 29, 2018

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see* §8057-A(1)(A)&(C)]
This rule-making proposes to amend Chapter 24 to make clarifying changes, including improving and creating definitions as necessary, using consistent terminology, and providing updates throughout the chapter. The rule-making also allows the Commissioner, in consultation with the Aquatic Animal Health Technical Committee, to issue permits to an approved quarantine facility from facilities that do not otherwise meet the regulation requirements, under certain limited circumstances.

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

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B)&(D)]
The proposed rule would modify the transfer permitting process under certain limited circumstances. Specifically, the proposed rule allows for consideration of evidence other than direct testing lots to provide evidence of disease freedom from Ceratomyxosis, Whirling disease, and PKD if importation will be only in the form of embryos that have been iodine disinfected before and immediately after import, prior to the time of introduction to the waters of the receiving facility.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE
Consultation and feedback from staff who permit the importation of marine organisms.

ESTIMATED FISCAL IMPACT OF THE RULE: [*see* §8057-A(1)(C)]
Enforcement of these proposed amendments will not require additional activity in this Agency. These changes will be implemented by responsible staff in their routine work.

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)]