DEPARTMENT OF MARINE RESOURCES

Chapter 24: IMPORTATION OF LIVE MARINE ORGANISMS

INDEX

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. **"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.

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

4. **"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.

5. **"Broodstock"** means reproductively mature aquatic animals that have been selected or used as part of a defined breeding program (See each species group for size definitions).

6. **"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.

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

8. **"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.

9. **"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.

10. **"Finfish"** is defined as live fish, fish 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.

11. **"Fish culture facility"** means an establishment where finfish are raised 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.

12. **"Gadid"** means fish in the family Gadidae.

13. **"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).

14. **"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).

15. **"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.

16. **"Inspection"** means an on-site, statistically-based sampling of all lots of fish 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.

17. **"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 aquatic animal health or transfer in the state from which the marine organisms originate. No marine organism culture facility owner or employee with direct supervisory authority over a facility may serve as an inspector for their 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.

18. **"Introduce"** means to bring into or deposit in any waters of the State from any restricted areas within the State of Maine.

19. **"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.

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

21. **"Northeast Fish Health Committee Guidelines"** means the most current available edition of the Northeast Fish Health Committee (NEFHC) Guidelines for Fish Health Management in Northeastern States.

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

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

24. **"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.

25. **"Pathogens of Regulatory Concern"** means infectious agents that may cause significant morbidity and/or mortality among marine organism populations in the State of Maine. Known pathogens of regulatory concern are classified by the Commissioner into two (2) pathogen categories 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. **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.

26. **"Pleuronectid"** means fish of the family Pleuronectidae.

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

28. **"Salmonid"** means fish of the family Salmonidae.

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

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 any live marine organisms whether indigenous or nonindigenous, without a permit issued by the 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.

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, 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 marine organism or to possess any such organism, must apply for a permit from the Commissioner. Application for a permit shall be submitted on forms supplied by the Commissioner and shall contain all information required by the 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 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 culture facility, if any;

5. Date of proposed import or introduction;

6. Nature, duration and purpose of 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 Northeast Fish Health Committee Guidelines.

24.06 Permit Application for Shellfish Used as Broodstock in Hatcheries

Any person who wishes to import or introduce any live shellfish for use as broodstock in a shellfish hatchery or to possess any such shellfish must apply for a permit from the Commissioner. Applications shall contain all information required by the Commissioner including without limitation the information required by 24.05 1 through 7 and a description of the physical facilities and production protocols associated with the quarantine of 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 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 Broodstock

Any person issued a permit under 24.06 shall hold such broodstock in an approved quarantine facility within the hatchery. Effluent from hatchery tanks or other equipment holding 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 Shellfish

1. The Commissioner may grant a permit to import for introduction or introduce shellfish, or to possess such shellfish, only if 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 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 Oysters, (*Ostrea edulis).* All territorial waters in the areas listed below shall be a restricted area for the American oysters, *(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).

5) North of a line beginning at the southernmost point of Oak Island, south of Gun Point, Harpswell and continuing northeast to the southernmost tip of W Cundy Point, Harpswell (Quahog Bay and Ridley Cove).

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 may include any permit conditions necessary to protect indigenous marine life or its environment, including, but not limited to, quarantine of broodstock in closed system hatcheries in recipient areas, quarantine of F1 generation individuals in isolation from 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 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 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 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 may include any permit conditions necessary to protect indigenous marine life or its environment, including but not limited to, quarantine of broodstock, inclusive of effluent treatment, in the recipient area, quarantine of first generation progeny individuals in isolation from

the broodstock and small-scale introduction of second generation progeny individuals into the recipient area with continuing disease study.

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

5. In determining whether to issue a finfish permit the Commissioner shall also follow the 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 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 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 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 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 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 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. **Endemic/Limited Distribution Pathogens**

(1) When any endemic/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 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 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. 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: Reproductively mature fish used as broodstock.

C. **Compliance Reporting Requirements, Reporting and Permits**

(1) **Inspections**

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

(b) Live salmonid finfish taken from the wild shall be subject to isolation as defined in the 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 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. 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 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 salmonid finfish for sale or transferring salmonid 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 finfish during transfer.

(5) Salmonid finfish transferred for the purposes of immediate harvest for human consumption, or diagnostic inspection 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) Salmonid finfish may not be transferred between marine net-pen facilities without 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	Endemic/ Limited Distribution	Exotic	Endemic/ Limited Distribution	Exotic	Endemic/Limited Distribution
Active Surveillance	VHSV IHNV ISAV-DEL	IPNV BKD	VHSV IHNV ISAV-DEL	IPNV	VHSV IHNV WD ISAV-DEL	BF BR IPNV 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-HRP0 Other

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

(1) 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 finfish received from qualified sources/hatcheries will not invalidate that fish culture facility's annual inspection status.

(f) Lots of fish finfish received 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
SPDV	Salmonid Pancreatic Disease Virus
OTHER	Any agent not detected in Maine as of the effective date of these rules that produces a cytopathic effect in cell culture during inspection.

2. Endemic/Limited Distribution 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.

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. 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). Sampling must be conducted monthly for all active salmonid facilities. 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, 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.

(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 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 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 established in 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" (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.

(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(18)(A)).

(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 marine finfish to any fish culture facility in Maine or stock marine 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 or 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 marine finfish for the purposes of stocking into coastal waters of Maine shall provide a fish health inspection report stating that such finfish have been inspected for all diseases of regulatory concern before a permit to engage in such activity is issued.

(2) 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 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 marine finfish into the State of Maine shall demonstrate that the finfish being imported are free from evidence of all diseases of regulatory concern, and originate from a qualified source/hatchery. The Commissioner may prescribe additional fish health testing requirements for importation of finfish into the State of Maine. A copy of the current approved transfer permit shall accompany the finfish during transfer.

D. Any person offering finfish for sale or transferring 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 finfish during transfer.

E. Finfish transferred for purposes of immediate harvest for human consumption, or diagnostic inspection shall not be subject to the provisions of these rules. 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. Finfish may not be transferred between marine net-pen facilities without a marine transfer permit.

24.32 Gadids (Fish in the family Gadidae)

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

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 agent not detected in Maine as of the effective date of these rules that produces a cytophathic effect in cell culture during inspection.

B. Endemic/Limited Distribution pathogens include:

IPNV	Infectious Pancreatic Necrosis Virus
ISAV-HPR0	Infectious Salmon Anemia Virus (HPR-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.

3. **Testing Requirements for 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	Endemic/Limited Distribution	Exotic	Endemic/Limited Distribution	Exotic	Endemic/Limited Distribution	Exotic	Endemic/Limited Distribution
Active Surveillance	VHSV IHNV ISAV-DEL La02β Other	BF IPNV Nodavirus Loma Histology for General Baseline	Biosecurity audits quarterly		VHSV IHNV ISAV-DEL	IPNV Nodavirus Other	VHSV IHNV ISAV-DEL La02β Other	BF IPNV Nodavirus Loma
Passive Surveillance	GID Other	ISAV-HPR0 Other	VHSV IHNV ISAV-DEL Other 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. 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.

   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, 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 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 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 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)

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 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 agent not detected in Maine as of the effective date of these rules that produces a cytopathic effect in cell culture during inspection.

B. 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.

3. **Testing Requirements for 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	Endemic/Limited Distribution	Exotic	Endemic/Limited Distribution	Exotic	Endemic/Limited Distribution	Exotic	Endemic/Limited Distribution
Active Surveillance	VHSV IHNV ISAV-DEL La02β Other	BF IPNV Nodavirus Loma General Parasitology Histology for general baseline	Biosecurity audits quarterly		VHSV IHNV ISAV-DEL	IPNV Nodavirus Other	VHSV IHNV ISAV-DEL La02β Other	BF IPNV Nodavirus Loma General Parasitology Histology for general baseline
Passive Surveillance	GID Other	ISAV-HPR0 Other	VHSV IHNV ISAV-DEL La02β Other 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. **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.

   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 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 broodstock, lethal sampling to continue testing history should come from other fish from the same lot not being used for broodstock.

(e) For marine net-pen facility cultured 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 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 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 Estuaries east & Gulf Coast)	NJ, DE, MD, VA, NC
D	Haplosporidium nelsoni (MSX)	CSN, DB, DE, CMA CGM* Marsh River, ME	NJ, NY, DE, MD, VA, 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 CSM, CGM?	All but ME
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	

EFFECTIVE DATE:

August 13, 1984

AMENDED:

November 19, 1990	
August 8, 1992 -	Section 10(D)(6)
December 9, 1992 -	Section 10(D)(6)
July 28, 1999 -	Section 21 added
November 29, 1999 -	Section 23 added.
September 10, 2001 -	Section 21(I and J) - EMERGENCY, filing 2001-390, expires December 9, 2001.
December 5, 2001 -	Section 21(H)(1) - EMERGENCY
December 23, 2001 -	Section 21(I and J)
February 9, 2002 -	Section 21(H)(1)(b) and (c)
August 21, 2002 -	Section 21(J) - EMERGENCY
October 21, 2002 -	Section 21(J)
July 20, 2009 -	01, 04, 05, 15, 16, 21, & Appendix A amended, 25 removed
October 11, 2010 –	Section 24.10(1)(D)(6), EMERGENCY
December 20, 2010 –	Section 24.10(1)(D)(6),
August 3, 2013 –	Section 24.10(1)(D)(6), EMERGENCY
October 17, 2013 –	Section 24.10(1)(D)(6),
January 21, 2015 –	Section 24.10(1)(D)(4), EMERGENCY
March 9, 2015 –	Section 24.10(4)(F), also, Section renumbered.
August 21, 2018 –	Sections .01; .03-.07; .10, .15-.17, .21, .30, .32, .34, Appendix B removed
February 14, 2021 –	Section .10(4)(F)(5) EMERGENCY
August 10, 2021	Section .10(4)(F)(5) EMERGENCY