DEPARTMENT OF MARINE RESOURCES

CHAPTER 24 - IMPORTATION OF LIVE MARINE ORGANISMS

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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 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 mature aquatic animals and/or preselected future broodstock. (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 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. "Finfish" is defined as live fish, fish eggs, or fish gametes, but does not include aquarium species commonly sold in the pet store trade when raised in indoor containers.

9. “Fish culture facility” means an establishment where finfish are grown for live sale and release into coastal waters of the State of Maine.

10. “Gadid” means fish in the family Gadidae.

11. "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.

12. “Inspection” means an on-site, statistically-based sampling of all lots of fish on 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. “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 health or fish transfer in the state from which the fish or gametes originate. No marine fish 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. "Introduce" means to land on, bring into or deposit in any place subject to the jurisdiction of the State of Maine from any restricted areas within the State of Maine.

15. "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. “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. “New England Fish Health Committee Guidelines” means the most current available edition of the New England Fish Health Committee Guidelines.

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

20. “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. “Pathogens of Regulatory Concern” means infectious agents that have been demonstrated to cause significant morbidity and/or mortality among marine organism populations in the State of Maine. Pathogens of Regulatory Concern are classified by the Commissioner into three (3) 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: 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. “Pleuronectid” means fish of the family pleuronectidae.

23. “Prevalence” means the number of detectable cases of disease (or disease agents) present in a population.

24. “Salmonid Fish” means fish of the family Salmonidae.

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

26. “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. 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 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.

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 or to possess any such shellfish or finfish, 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 shellfish or finfish to be imported or introduced;

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

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

5. date of proposed 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.

9. a valid fish health inspection report issued by a fish health inspector in accordance with the New England Fish Health Committee Guidelines and particularly the Guidelines for Importation.

24.06 Permit Application for Shellfish Used as Brood Stock in Hatcheries

Any person who wishes to import or introduce any live shellfish for use as brood stock 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 A through G and a description of the physical facilities and production protocols associated with the quarantine of brood stock 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 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

Any person issued a permit under 24.06 shall hold such brood stock in quarantine within the hatchery. Effluent from hatchery tanks or other equipment holding brood stock 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 or introduce shellfish, or to posses such shellfish, 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 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 may include any permit conditions necessary to protect indigenous marine life or its environment, including, but not limited to, quarantine of brood stock in closed system hatcheries in recipient areas, quarantine of F1 generation individuals in isolation from brood stock 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 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 brood stock, inclusive of effluent treatment, in the recipient area, quarantine of first generation progeny individuals in isolation from the brood stock 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 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 shall also follow the New England 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” 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 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 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. 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 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 relevant facts 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 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 Pathogens

      (1) When any reportable 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 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) It is unlawful to transfer live salmonid gametes or fish to any fish culture facility in Maine or stock salmonid fish or gametes into the coastal waters of Maine that do not meet the requirements of these rules.

(2) No clinically diseased salmonid fish 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 salmonids or gametes for the purposes of stocking into coastal waters of Maine shall provide a fish health inspection report stating that such salmonid fish or gametes 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 taken from the wild shall be subject to isolation as defined in the New England 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 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) Any person applying for a permit to import live salmonids or gametes into the State of Maine shall demonstrate that the fish or gametes being imported are free from evidence of all pathogens of regulatory concern; that the fish or gametes are from a source 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 during transfer.

(4) Any person offering live salmonids or gametes for sale or transferring live salmonids or gametes 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 during transfer.

(5) Live salmonid fish or gametes transferred for purposes of immediate harvest for human consumption, 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 may not be transferred between marine sites without an ocean site to ocean site 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 Reportable		Exotic Reportable	Endemic, limited distribution Reportable		Exotic Reportable	Endemic, limited distribution Reportable
Active Surveillance	VHSV IHNV ISAV	IPNV BKD		VHSV IHNV	IPNV		VHSV IHNV WD ISAV	BF BR IPNV BKD
Passive Surveillance	OMV CS WD PKD SPDV Other	BF BR Other		OMV CS PKD SPDV Other	BF BR BKD		OMV CS PKD SPDV 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.

(2) Fish health inspections shall be conducted at a time or times of the year conducive for the detection of pathogens 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 received from qualified sources/hatcheries will not invalidate that fish culture facility's annual inspection status.

(f) Lots of fish and/or gametes 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 Infectious Salmon Anemia Virus
   SPDV Salmonid Pancreatic Disease Virus
   OTHER Any pathogen not detected in Maine as of the effective date of these rules.

2. Reportable pathogens include:
   IPNV Infectious Pancreatic Necrosis Virus
   BKD Bacterial Kidney Disease (Renibacterium salmoninarum)
   BF Furunculosis (Aeromonas salmonicida)
   BR Enteric Redmouth (Yersinia ruckeri)

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 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. 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 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 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.

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

B. No clinically diseased fish 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 for the purposes of stocking into coastal waters of Maine shall provide a fish health inspection report stating that such fish or gametes have been inspected for all diseases of regulatory concern before a permit to engage in such activity is issued.

(2) Live fish or gametes 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 should be selected during the movement event for testing as prescribed for size group 2 of the relevant species.

B. Any fish 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.

C. Any person applying for a permit to import live marine fish or gametes into the State of Maine shall demonstrate that the fish or gametes being imported are free from evidence of all diseases of regulatory concern, and originate from a source 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 into the State of Maine. A copy of the current approved transfer permit shall accompany the fish or gametes during transfer.

D. Any person offering live fish or gametes for sale or transferring live fish or gametes 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 during transfer.

E. Live fish or gametes transferred for purposes of immediate harvest for human consumption, diagnostic inspection or related laboratory research shall not be subject to the provisions of these rules. Fish 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 may not be transferred between marine sites without an ocean site to ocean site 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. “Production stock” means Gadid fish of size groups 1 and 2.

C. “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 Infectious Salmon Anemia Virus

GID *Francisella species* – granulomatous inflammatory disease
La02β *Listonella (Vibrio) anguillarum* serotype and 02 beta
OTHER Any pathogen not detected in Maine as of the effective date of these rules.

B. Reportable pathogens include:
IPNV Infectious Pancreatic Necrosis Virus
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*.)

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 for Diseases 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	Exotic	Reportable	Exotic	Reportable	Exotic	Reportable
Active Surveillance	VHSV IHNV ISAV La02β Other CPE agents	BF IPNV Nodavirus Loma Histology for General Baseline	Biosecurity audits quarterly		VHSV IHNV ISAV	IPNV Nodavirus Other CPE agents	VHSV IHNV ISAV La02β Other CPE agents	BF IPNV Nodavirus Loma
Passive Surveillance	GID Other	Other	VHSV IHNV ISAV Other CPE agents GID La02β	Nodavirus IPNV BF Loma Other	La02β GID Other	BF Loma Other	GID Other	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. 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 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 brood, 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 brood 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 Marine site cultured selected brood fish, 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 quarantine 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 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 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 Halibut

A. Exotic pathogens include:

IHNV	Infectious Hematopoietic Necrosis Virus
VHSV	Viral Hemorrhagic Septicemia Virus
ISAV	Infectious Salmon Anemia Virus
GID	*Francisella species* – granulomatous inflammatory disease
La02β	*Listonella (Vibrio) anguillarum* serotype 02 beta
OTHER	Any pathogen not detected in Maine as of the effective date of these rules.

B. Reportable pathogens include:
IPNV Infectious Pancreatic Necrosis Virus
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*.)

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 for Diseases 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	Exotic	Reportable	Exotic	Reportable	Exotic	Reportable
Active Surveillance	VHSV IHNV ISAV La02β Other CPE agents	BF IPNV Nodavirus Loma General Parasitology Histology for general baseline	Biosecurity audits quarterly		VHSV IHNV ISAV	IPNV Nodavirus Other CPE agents	VHSV IHNV ISAV La02β Other CPE agents	BF IPNV Nodavirus Loma General Parasitology Histology for general baseline
Passive Surveillance	GID Other	Other	VHSV IHNV ISAV La02β Other CPE agents GID	Nodavirus IPNV BF Loma Other	La02β GID Other	BF Loma Other	GID Other	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. 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 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 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 brood, 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 brood health history.

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

(e) For Marine site cultured brood fish, 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 quarantine 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 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 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

DEPARTMENT OF MARINE RESOURCES

CHAPTER 24 - IMPORTATION OF LIVE MARINE ORGANISMS

INDEX

EFFECTIVE DATE:

August 13, 1984

AMENDED:

November 19, 1990
August 8, 1992 – Section 10(D)(6), EMERGENCY
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
December 5, 2001 – Section 21(H)(1)(b) and (c), 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 – Sections 01, 04, 05, 15, 16, 21, & Appendix A amended; Section 25 removed; Sections 30, 32, 34 & Appendix B added
October 11, 2010 –Section 10(1)(D)(6), EMERGENCY
December 20, 2010 –Section 10(1)(D)(6) & Appendix A amended
August 3, 2013- Section 10(1)(D)(6)(a)&(b) added, EMERGENCY. Expires Nov. 1, 2013
October 17, 2013-Section 10(4)(F)(1)&(2) added; same text and section as emergency rule; renumbered.
January 21, 2015-Section 10(4)(F)(2) amended; (3)(4) added; EMERGENCY. Expires April 21, 2105.
March 9, 2015- Section 10(4)(F)(2) amended; (3)(4) added