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New Jersey Agricultural Experiment Station

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RECOMMENDED MANAGEMENT PRACTICES FOR AQUATIC FARMS

AGRICULTURAL MANAGEMENT PRACTICES (AMPS)
AQUATIC ORGANISM HEALTH MANAGEMENT PLAN

COOK COLLEGE
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Recommended Agricultural Management Practices

Introduction

The Agricultural Management Practices (AMPs) in this manual are recommended for use by all holders of Aquatic Farmer Licenses. The farmer is also required to obtain any and all permits required by the appropriate state regulatory agencies (i.e. NJDEP). Adherence to these AMPs does not exempt an aquatic farmer from other applicable agency permits.

More in depth information can be found in ***A Guide to Developing Aquatic Farms in New Jersey.*** This document is available from the New Jersey Department of Agriculture. For additional information about the Agricultural Management Practices, please contact: NJDA, Office of Aquaculture Coordination at (609) 984-6757

AMPs are intended to preserve environmental integrity. They are designed to assist aquatic farmers in complying with appropriate environmental regulations and facilitate the permitting process. Aquatic farmers following these recommended practices will more easily satisfy the standards necessary for protecting and maintaining offsite water quality and wildlife habitat.

A set of Agricultural Management Practices (AMPs) stressing good production practices can provide significant economic benefits to aquatic farmers and substantially improve bottom line profits. Good management practices can protect the natural environment, native fish stocks, reduce disease and mortality in aquatic farms, improve the quality of farm-raised products, allow the producer to achieve a greater economic return, potentially reduce the cost of permitting, and reduce the cost of remediation and rehabilitation.

The AMPs listed in this manual do not supersede other applicable state and federal regulations or resource collection authorizations. Therefore, aquatic farmers need to be aware of the pertinent environmental regulations that affect navigability, wetlands, waste disposal, worker safety, endangered species, water quality, water supply, native stocks, waterfront development, CAFRA, and stream encroachment. Additional Management Practices are found in the Aquatic Organism Health Management Plan.

I. Federal Permits

The United States Army Corps of Engineers (ACOE) regulatory program is one of the oldest in the Federal Government and is empowered by the Rivers and Harbors Act of 1890 which establishes permit requirements to prevent unauthorized obstruction or alteration of any navigable water of the United States. This navigable water's jurisdiction, also known as the territorial waters or the Exclusive Economic Zone (EEZ), includes all ocean waters three nautical miles to 200 miles from the coastline on the East Coast. Section 10 of this act covers construction, excavation, or deposition of materials in, over, or under such waters which could affect the course, location, condition, or capacity of those waters. Section 9 of this act routinely applies to dams and dikes.

The Federal Water Pollution Control Act as amended in 1977 and commonly referred to as the Clean Water Act (CWA), includes section 404 authorizing the Secretary of the Army, acting through the Chief of Engineers,

to issue permits for the discharge of dredged or fill material into waters of the United States. Section 404 jurisdiction is defined as "encompassing the territorial seas plus their tributaries, adjacent wetlands, and isolated waters where the use, degradation or destruction of such waters could affect interstate or foreign commerce." While the ACOE acts as the lead permitting agency, the Environmental Protection Agency has veto powers and may invoke this authority at any time.

The basic form of authorization used by the ACOE is the Individual Permit. Another form of authorization is the General Permit which typically covers activities the ACOE has identified as substantially similar in nature and causing only minimal environmental impacts. Nationwide General Permits (33CFR part 330, Appendix A-Fish and Wildlife Harvesting, Enhancement and Attraction Devices and Activities) may be applicable to some aquaculturists.

II. Construction

Site Selection

Consider previous use of the site to evaluate the potential for the presence of latent agricultural or industrial contamination.

AGRICULTURAL MANAGEMENT PRACTICES

- Consider previous history of the site.
- Soil samples.

Erosion Control Guidelines

During the construction phase of the project, care must be taken to prevent or control erosion and sediment deposition and potential adverse effects downstream from the facility. Sediment loads to aquatic environments can block waterways, kill aquatic plants, reduce oxygen levels and be detrimental to users downstream. Sediments from storm water runoff may also be associated with the transport of unwanted chemicals and nutrients to aquatic environments. Be sure to obtain all construction permits before site clearing and construction commence.

AGRICULTURAL MANAGEMENT PRACTICES

- Select a site where the natural drainage patterns can be incorporated into the facility design to move water more effectively.

- If you plan to disturb more than 5,000 sq. ft. of soil for the purpose of building construction, it is necessary to contact your local soil conservation district.

- Use swales and/or berms to direct overland and stormwater through, or around your property in order to maintain natural drainage patterns. Criteria for these and other surface water control techniques can be obtained from the local Natural Resources Conservation Service (NRCS) office or the NJDEP.

- Stabilize exposed soils by providing vegetative cover to prevent erosion and inadvertent filling of wetlands and their associated transition areas by sedimentation. Consult NRCS or NJDEP for guidance.

- Aquatic farms should be designed to control stormwater and minimize erosion.

- Ponds should be designed in accordance with State and Federal Standards and constructed at an elevation above the 100-year flood zone.

- Standards and design criteria for erosion control, ponds, and water control structures can be found in the Field Office Technical Guide and the Engineering Field Manual of the Natural Resources Conservation Service (NRCS) or the NJDEP and modified for aquaculture use. Local offices of NRCS are found throughout the State.

- Regulations in the Pinelands area, in most instances, limit off site removal of excavated materials as an accessory to an aquatic farm. A separate application must be made to the Pinelands Commission for such removal.

III. Shipment, Transportation and Sale

During shipment and transportation, care must be taken so that potential for escape is minimized and State laws are met in the identification of products. The following AMPs will apply to all licensed aquatic farmers.

AGRICULTURAL MANAGEMENT PRACTICES

- Any aquatic organisms that have been produced in an aquatic farm in New Jersey and are being transported for sale or distribution to another location shall be accompanied by a bill of sale, receipt or bill of lading. Any aquatic organism being transported and not for sale or distribution shall be accompanied by a copy of the valid New Jersey Aquatic Farmer License issued by NJDA. All documentation must include the license number of the production facility.

- Any shipments from out of the State must conform to the regulations for importation of aquacultured products.

- Any label, receipt, bill of sale or bill of lading shall contain the name and address of the shipper, license number of receiver, and the identity of the aquatic organisms by species, total weight, or number.

- Any product being shipped to a New Jersey aquatic farm must be accompanied by the license number of the receiver.

- In the case of molluscan shellfish, any firm that sells, stores or processes aquacultured molluscan shellfish for human consumption must possess a shellfish dealer certification and meet all applicable provisions under NJAC 8:13-1 et seq.

- Records must be retained and made available for inspection by the hatchery or farm for a minimum of two (2) years.

- Any firm that sells, stores or processes aquacultured seafood or seafood products for human consumption must possess a wholesale food license as specified under NJSA 24 and must meet the requirements of NJAC 8:13-2 et seq., titled Sanitation in Food and Non-Alcoholic Beverage Establishments.

- Any shipments from out of State must contain the Aquatic Farmer License number of the farm/facility (if applicable) that is receiving the shipment and the Aquatic Farmer License or permit number of the shipper (if applicable). Any shipment leaving the State must contain the Aquatic Farmer License number of the farm/facility sending the shipment.

IV. Water Resources

AMPs in this section serve as general guidelines to the aquaculturist. Please note that NJPDES regulations/ permits may be applicable in certain instances upon NJDEP review of the project. Adherence to these AMPs does not exempt an aquaculturist from other permits including NJPDES permits.

This section is broken down into six parts; some, all or none of which may apply to your farm:

1) Effluent Treatment

2) Water Quality Treatment and Attenuation Criteria

3) Wetlands Protection

4) Special Water Resource Considerations

5) Water Supply Considerations

6) Saltwater Considerations

1) EFFLUENT TREATMENT

Except for indirect discharges, aquaculture facilities must adhere to the following AMPs regarding discharge of culture water.

Exemptions:

Molluscan Shellfish Facilities:

Culture water of operations that produce filter feeding molluscan shellfish exclusively. This refers to operations where no feed and/or other additives are being put into the water that will eventually be discharged to waters of the State or placed directly into the waters of the State. Molluscan shellfish operations that do feed algae or use less than the threshold amounts stated at N.J.A.C.7:14A-2.14 that trigger the need for permits are exempt.

For Cold Water Fish Culture:

Facilities that feed **less than** 5,000 lbs. (2,268 kg) of feed during the calendar month of maximum feeding: and

Facilities that produce **less than** 20,000 lbs. (9,072 kg) of cold water (marketable product) finfish per year.

For Warm Water Fish Culture:

Closed ponds with no discharge.

Facilities that produce **less than** 100,000 lbs. (45,360 kg) of warm water (marketable product) finfish per year.

All other aquatic farms that discharge to surface and groundwaters of the State must adhere to the following AMPs:

Effluent or production water discharge from culture systems normally contain suspended and settleable solids, both organic and inorganic, as well as dissolved compounds as a result of feeding and other farm activities. One of the most effective means of reducing the level of pollutants in the effluent is to carefully manage the feeding program. This not only reduces the cost of treating the effluent but also saves money on the cost of feed. It is necessary to manage aquaculture effluent to prevent or minimize environmental impact to receiving waters. Because of the variety of production systems (i.e. ponds, cages, net pens, tanks and raceways) and stocking rate, feed type and intensity, combined with variable site characteristics; several options in management of effluents are recommended as AMPs.

AGRICULTURAL MANAGEMENT PRACTICES

- In designing flow-through systems, provisions should be made to allow for quiescent zones which can serve as a settling area for solids. To reduce turbulence, wire mesh screen should be used to prevent fish from entering the quiescent zones.

- Filter strip option: Treatment of effluent by passing it through a constructed "filter" strip (basin) prior to discharge to waters of the State is an effective means of reducing a variety of effluent pollutants. A constructed strip of vegetated land is designed such that water will flow in a thin sheet slowly across it. This strip allows for capture of sediment, organic matter and other pollutants by deposition, infiltration, absorption, decomposition, and volatilization. NRCS may be consulted for guidance on the design and implementation of such filter strip systems. In the Pinelands, filter strips of up to 300 feet are required. The one exception is the horticulture of native Pinelands aquatic plants.

- Detention facility option: Treatment of effluent prior to discharge to waters of the State by detention or temporary (no more than 30 days) storage in a pond or ditch system is an acceptable practice. The detention ponds can be aerated to improve water quality prior to discharge.

- Wetland treatment option: Discharge of effluent into or through a constructed wetland prior to discharge to surface waters of the State may provide an effective and environmentally sound means of providing additional treatment. Consult NRCS, NJDEP Land Use, or NJDEP Water Quality for guidelines. This option may not be approved for the intended site (i.e. Pinelands area). Please check with the appropriate State agency to ascertain State requirements on a particular parcel of land.

- Integrated production option: Effluent from aquaculture production units can be re-used for the purposes of producing a secondary aquaculture crop, agriculture crops or aquatic plants or

combinations thereof. This option allows for numerous design opportunities including water recirculation. This practice may provide sufficient remediation to permit the release of final effluent with no further treatment or at least allow a considerable reduction in the complexity of the treatment stages.

- Retention option or zero surface water discharge: Retention of all production unit effluent on site is considered proper management of effluent. This may be a viable option for certain facilities and can be accomplished by a variety of methods including:

    1. Retention, evaporation or percolation in ponds. In site locations where the soil is highly porous and will allow water infiltration, a pond may be constructed to hold all required discharge and allow for percolation. The volume of the pond is determined by the expected quantity of discharge and the evaporation and percolation rate of the soil as determined by the USDA NRCS soil survey data or independent testing.

    2. Field Application. Applying effluent (freshwater only) to fields for irrigation purposes is an acceptable method in handling production unit discharges and should be based on Rutgers Extension's Nutrient Management Plan. Field application is generally most suitable where soils are highly porous and where irrigation would likely be an advantage relatively soon after rain has occurred.

    3. Septic System. In those situations where the effluent volume and the rate of discharge is appropriate, a septic system is a suitable option for handling effluent.

    4. Direct discharge to a sanitary sewer where permitted and feasible.

- Other water quality enhancement practices: Several management practices exist which can be utilized in conjunction with the treatment options to improve water quality of effluent.

    These include:

    1) Aeration within detention facility to increase dissolved oxygen, volatilization of gases and enhanced bacterial oxidation of organic matter.

    2) Use of biological filtration to enhance conversion of ammonia to nitrite and finally to nitrate. This practice has potential for small volumes of water such as small tank production systems.

    3) Chemical treatments may be effective to reduce concentrations of certain parameters of concern such as using alum to reduce clay turbidity, and addition of beneficial bacteria supplements to enhance organic matter oxidation and other nutrients.

2) WATER QUALITY TREATMENT AND ATTENUATION CRITERIA

Stormwater Sources and Management

Before settling on a final design for the facility, consider the following issues and the impact each may have on the design and the impact the design may have on the site and on surrounding properties.

To determine whether or not the site is subject to problems associated with excessive run off, consider the following conditions:

Where and how much water flows onto the property?

Where and how much water flows off the property?

What are the predominant soil types on the property?

What is the absorption/percolation capacity of the surface soils and substrate?

Are the soils susceptible to excessive runoff?

Are there steep slopes on or adjacent to the site?

How much new impervious surface is being added to the operation/property?

Will the proposed activity significantly increase or decrease the volume and timing of stormwater flowing from the property to adjacent lands or water bodies?

AGRICULTURAL MANAGEMENT PRACTICES

- Where appropriate, incorporate in the final design and any design modifications, features that would minimize the potential impacts of commingling surface water and production water.

- Utilize and adhere to the recommendations in the Erosion Control Guidelines of the Construction chapter of this AMP manual before starting construction.

- Know the operation. Proper characterization of production pond water effluent, fully employing the other water quality AMPs enumerated in this manual and having a good understanding of local rainfall patterns will assist in terms of design efficiency.

- If possible, construct the facility at grade or above.

Industry Specific Criteria

Besides complying with the specific criteria outlined below, aquatic farmers should also comply with all AMPs appearing in sections that pertain to them. For purposes of this AMP manual, the water quality and attenuation (flood protection) criteria have been grouped together; moreover, rather than deal with each aquaculture sector separately, the criteria are further segmented and arranged on the basis of pond systems and recirculating intensive aquaculture systems. Please note that those facilities utilizing salt or brackish water will have unique discharge characteristics that will reduce or eliminate some of the effluent discharge options.

Earthen Aquaculture Systems

There are 2 subcategories here:

Category # 1: New construction of excavated ponds

AGRICULTURAL MANAGEMENT PRACTICES

- Ponds must be constructed in accordance with the USDA-NRCS guidelines or an NJDEP approved engineering design and should maintain adequate freeboard to prevent effluent overflow during periods of heavy rain.

- For construction of ponds in the Pinelands, a separate application must be made to the Pinelands Commission for the off-site removal of excavated material as an accessory to an aquacultural use.

- Generally, ponds should be constructed not to discharge; ponds expected to discharge should demonstrate that production water discharges are capable (via the entire surface water management system) of providing a one day or five-day residence time that has been demonstrated to adequately reduce the controlled/regulated components in the discharge to a level that will not compromise the quality of the receiving water.

- For maintenance or harvesting purposes, scheduled pond drawdown(s) should be routed to existing surface water management facilities or distributed to adjacent aquaculture ponds on-site. Care should be taken not to transfer predators or parasites to "clean" ponds when such operational strategies are utilized.

Category #2: New construction of above ground levee ponds

AGRICULTURAL MANAGEMENT PRACTICES

- Ponds must be constructed in accordance with the USDA-NRCS guidelines or an NJDEP approved engineering design and should maintain adequate freeboard.

- When draining ponds, NJDEP Water Quality guidelines for effluents must be adhered to and followed.

- Routinely maintain pond/dike facilities to minimize seepage.

- For maintenance or harvesting purposes, scheduled pond drawdown(s) shall be accomplished in the following manner:

    1) Only drain pond(s) for harvesting and maintenance as necessary,
    2) Drain the pond(s) during the dry season or times of low rainfall when possible,
    3) For maintenance or harvesting purposes, scheduled pond drawdown(s) should be routed to existing surface water management facilities or distributed to adjacent aquaculture ponds which are on-site.

Recirculating/Intensive Aquaculture Systems

These systems generally rely on the construction of permanent structures, recirculation apparatus, tanks, and other features. These systems treat and reuse all or a major portion of their production water. While the volume of effluent from a recirculating system does not typically approach the quantity associated with the more traditional forms of aquaculture, the concentration of nutrients associated with the effluent is usually greater.

- Design the system for no direct off site discharge of production water. Effluents may either be treated and retained on a site, or discharged to a permitted sanitary sewer system. Treatment techniques include, but are not limited: to percolation ponds, irrigation systems, constructed wetlands, or filter strips. These techniques may be utilized either individually or in combination. Please note: discharging production water to a sanitary sewer system will require authorization/permitting from the local sewage/wastewater treatment authority and potentially NJDEP.

- Design a waste treatment system to handle the semi-solid waste stream and non-recycled production effluent from filters and solids separators. Dispose of waste solids in a legal manner that will not cause environmental degradation. For more information, see the NJDA's Animal Waste Management Plan. Potential options for solids treatment and disposal include composting followed by appropriate land application as a soil amendment or disposal at a sanitary landfill.

- Maintain filter systems for optimum water quality.

3) WETLANDS PROTECTION

Wetlands are important components of New Jersey's water resources:

- They serve as spawning areas and nurseries for many species of fish and wildlife,
- They provide storage of flood waters,
- They take up nutrients in runoff water,
- They provide habitat for plant and animal diversity,
- They provide recreational opportunities for the public.

Wetlands are complex transitional ecosystems between aquatic and terrestrial environments.

Elimination / Reduction of Wetland Impacts

Wetlands exist as isolated features in the landscape or contiguous flowing watercourses within a defined channel or within a discernable shoreline. The AMPs are designed to protect wetlands from adverse impacts associated with dredging, filling, hydro-period alteration, expansion or reduction of watersheds, or degradation of water quality. **Do not conduct dredge and fill activities in wetlands or wetland buffers as defined by NRCS, Pinelands, or NJDEP.**

AGRICULTURAL MANAGEMENT PRACTICES

- Contact the NRCS, local soil conservation district, or NJDEP to confirm the absence or presence of on-site and adjacent off-site wetlands prior to initiating any aquacultural design or construction

activities. Once detected, a Letter of Interpretation can be issued from NJDEP, in regards to presence and classification of wetlands.

- All new construction must maintain a minimum upland buffer of 150 feet from the boundary of all wetlands and or perennial watercourses. In the Pinelands, required buffers may be up to 300 feet.

- A Coastal Wetlands Permit is needed to excavate, dredge, fill or erect structures on coastal wetlands as delineated in maps promulgated by the NJDEP pursuant to the Wetlands Act of 1970.

- The Freshwater Wetlands Protection Act seeks to protect freshwater wetlands. State open waters (waters of the United States which are not wetlands) and upland areas up to 150 feet (300 feet in the Pinelands) from wetlands serve as buffers from random, unnecessary or undesirable alteration or disturbance. For more information, please contact the NRCS, your local soil conservation district or NJDEP to find out if you will conduct activity within 150 (300) feet of a freshwater wetland.

Production Water Discharges into Constructed Wetlands

Constructed wetlands may be used for water quality treatment purposes provided the aquaculture facility owner and the owner/operator are operating the facility in compliance with all applicable AMPs.

AGRICULTURAL MANAGEMENT PRACTICES

- Use spreader swales and other devices to mimic treated sheetflow into wetlands.

- If your production exceeds 10,000 pounds per year, avoid direct discharge of any untreated effluents into wetlands.

- Use a controlled method of treated discharge to assure the flow into the wetland will mimic predevelopment flow patterns.

4) SPECIAL WATER RESOURCE CONSIDERATIONS

Borrow Pits

Mining operations throughout the State have resulted in the construction of many pit ponds in New Jersey. The vast acreage and tremendous water volume in these water bodies have sparked interest from prospective fish culturists. While these systems may be an inexpensive source of water, they may also involve challenges that other types of aquaculture systems do not. Limitations on biomass are necessary to minimize eutrophication and associated fluctuations in water quality. It is important to prevent overfeeding which is costly and can lead to water quality issues. Adhering to the following AMPs will assist you in maintaining water quality and decrease the chance of a catastrophic crop loss due to oxygen depletion. In addition, wetlands along borrow pit edges may be regulated under the Freshwater Wetlands Protection Act.

AGRICULTURAL MANAGEMENT PRACTICES

For borrow pits with a crop biomass of less than 2,000 pounds per surface acre:

- Limit feeding to a maximum of 5% of biomass per day.

- If non-native or restricted species will be cultured in the system, refer to the containment section of the "Non-Native and Restricted Non-Native Species" section of this manual.

For borrow pits with a crop biomass greater than 2,000 pounds per surface acre or ponds with feeding rates that exceed 5% of biomass per day:

- Utilize aerators, pumps, or other methods to eliminate pond stratification.

- Establish a feeding protocol that eliminates overfeeding.

- Use a cage system designed to minimize feed loss and to allow for the collection and removal of waste. Floating cage technology is encouraged.

- If non-native or restricted species will be cultured in the system, refer to the containment section of the "Non-Native and Restricted Non-Native Species" section of this publication.

5) WATER SUPPLY CONSIDERATIONS

Most, if not all, aquaculture facility operators will require a water source to either augment existing water supplies or provide makeup water in its entirety. This water source can be either groundwater, surface water, seawater or a combination of these.

A New Jersey licensed well driller of the proper class and permit is required to drill a well or to modify the physical construction of an existing well (i.e. well deepening or a new screen.). While a permit is not required for the sealing of any abandoned well, a NJ licensed well driller who is certified to seal wells is the only individual who can perform such work.

Water Supply Considerations – The State has currently identified two areas of the State as Water Supply Critical Areas. Critical Area 1 is located in portions of Middlesex, Monmouth and Ocean Counties. Water Supply Critical Area 2 is located in portions of Camden, Gloucester, Salem and Burlington Counties. State law prohibits water allocations being issued in critical aquifers within these areas. If projects are planned for these areas, the NJDEP Water Supply Administration should be contacted for guidance and information on what, if any, impacts the critical area restrictions will have on the planned facility.

Any agriculture, horticulture, or aquatic farm planning to use an average of 100,000 gallons of water per day for a month (i.e. a minimum of 3 million gallons a month) requires an Agricultural Water Certification. If a farmer has the pumping capacity for 70 gallons a minute or more but does not use 3 million gallons of water or more in any month then he/she is required to secure an Agricultural Water Registration from the NJDEP through a County Agent. The County Agricultural Agent at the Rutgers Cooperative Extension office provides all necessary forms and information and issues all new certificates. Renewal forms and information are also provided by the County Agent but all renewals are issued by the NJDEP Office of Water Allocation. One can use less than 3 million gallons of water a month without a certification. Use of water over this limit without a certification is illegal and subject to penalties.

AGRICULTURAL MANAGEMENT PRACTICES

- Any agriculture, horticulture, or aquatic farm planning to use an average of 100,000 gallons of water per day for a month (i.e. a minimum of 3 million gallons a month) requires an Agricultural Water Certification. This Certification is available from NJDEP through the County Agricultural Extension Agent.

- If a farmer has the pumping capacity for 70 gallons per minute or more but does not use 3 million gallons of water or more in any month then he/she is required to secure an Agricultural Water Registration from the NJDEP through the County Agricultural Extension Agent.

- One can use less than 3 million gallons of water a month without a Certification provided that he/she does not have pumping capacity of 70 gallons per minute. Use of water over this limit without a certification is illegal and subject to penalties.

6) SALTWATER SOURCES

There may be circumstances where aquaculture operations located adjacent to the coastline will need salt water to culture certain organisms, especially those organisms that may require an estuarine or marine environment during a portion of their life cycle (i.e. clam hatcheries). There are two potential environmental issues that may arise: 1) withdrawal of saline water and 2) potential impacts on freshwater systems by virtue of saline discharge effluent.

AGRICULTURAL MANAGEMENT PRACTICES

- Use a recirculating system technology, when appropriate, to avoid having an excess amount of either fresh or salt water leaving the site.

- Contact the NJDEP to find out about well drilling permits and activities.

- Contact the NJDEP to find out about areas that restrict the use of saltwater intake or discharge.

V. Non-Native and Restricted Non-Native Species

Non-native species means any species of plant or animal that does not occur naturally in the waters of the State.

Non-Native Species Containment

Aquaculturists who possess non-native species that may survive for a continuous 12- month period in our climate are responsible for preventing their release to the environment.

In the Pinelands Preservation District and Special Agricultural Production Areas, regulations limit agriculture to berry agriculture, horticulture of native plants and other agricultural activities compatible with the existing soil and water conditions that support traditional Pinelands berry agriculture. This provision will limit non-native species aquaculture in these two Pinelands management areas.

AGRICULTURAL MANAGEMENT PRACTICES

- All holding, transport, and culture systems will be designed, operated, and maintained to prevent the accidental or intentional release of non-native aquatic species into waters of the State.

- Non native species may not be sold as live 'baitfish' in New Jersey.

- Farm operators must adhere to import protocols set forth by either NJDA or NJDEP depending upon the type of system in which the organisms will be held.

Restricted Non-native species refers to all non native plant and animal species that have special possession regulations in New Jersey.

Restricted Non-Native Species Containment

All holding, transport and culture systems should be designed not only to prevent escapement of the species into the water, but also to prevent disease organisms, pests, and predators that may be associated with the cultured organism from entering the waters of the State. This also applies to screening or filtering of discharge systems.

Within the State of New Jersey, the sale of live restricted non-native species is limited to individuals with a valid Aquatic Farmer License for that species. Facilities culturing restricted non-native species must adhere to the following AMPs, as well as the AMPs listed for non-native species.

AGRICULTURAL MANAGEMENT PRACTICES

- Restricted non-native species cultured outdoors may only be held in a water body which has the lowest point of its levee, dike, bank, or tank at an elevation of at least one foot above the 100-year flood elevation as determined by elevation maps issued by the National Flood Insurance Program of the Federal Emergency Management Agency (FEMA).

- All holding, transport, and culture systems must consist of solid and physically stable construction and be designed to prevent the escape of adult fish, juvenile fish, and eggs.

- The facility must have measures in place to prevent the theft of restricted non-native species.

- Written records of live restricted non-native species purchases, sales and transfers must be maintained for a period of two years.

- Farm operators must adhere to import protocols set forth by either NJDA or NJDEP.

AGRICULTURAL MANAGEMENT PRACTICES FOR ALTERNATIVE CONTAINMENT

Any of these systems may be utilized as long as it meets the containment requirements above:

- No discharge or zero discharge production systems are designed to ensure that water from the production units is not discharged from the facility. This includes design parameters and management practices to ensure that storm water does not cause the system to discharge.

- Screened discharge systems utilize screen or filter devices at the point of production unit discharge, at the point of discharge from the operation or at the point of discharge from effluent treatment facility, such as a detention or retention pond. A variety of screen or filter designs and devices may be used to retain the smallest size fish or egg. Examples of screened/filter systems include a simple series (multiples are used to ensure at least one screen is in place while others are cleaned) of mesh screens capable of screening all water, a dry bed filter constructed of a container with gravel and sand to trap eggs and fish, a commercially available micro screen solids filter, or a pond trap with screened discharge. Intake pipes must also be screened.

- Filtering, disinfection or sterilization techniques may include ultraviolet light (UV), ozone or chlorine treatment systems. A combination of these treatment systems can also be used.

VI. Prohibited Species

Prohibited species are those plants and animals that are not eligible for culture and may not be possessed in New Jersey. For a list of prohibited species, contact the NJDEP Division of Fish & Wildlife.

AGRICULTURAL MANAGEMENT PRACTICES

- Anytime a prohibited species is discovered at a licensed facility, it is to be immediately disposed of according to the Mortality Removal/Disposal AMP in this manual or as advised by inspection authorities, or shipped to another locality where it is a permitted species using appropriate shipping protocols.

VII. Health Management

Good aquatic organism health is necessary for the success of any aquaculture production facility. A sound management and sanitation program will greatly reduce the risk of pathogens and disease on your farm. Disease prevention is based on the reduction of stress in the culture organism, exclusion of pathogens in the culture tank/pond and containment of sick animals/plants when a disease outbreak occurs. The following AMPs are intended to support and develop sustainable aquaculture.

AGRICULTURAL MANAGEMENT PRACTICES

- Contact the NJDA within 48 hours in the event of any unusual or abnormal occurrences of disease or pests affecting your aquatic species.

- Follow the New Jersey Aquatic Organism Health Management Plan.

- Use only drugs and other chemical agents that conform to FDA/EPA guidelines as defined by the product label, or listed as “drugs” of low regulatory concern.

- "Extra label" drug use requires prescription by a veterinarian and must comply with the AMDUCA rules established by the FDA.
- Dispose of chemical agents and containers in an appropriate, environmentally-sound manner as required by NJDEP.

AGRICULTURAL MANAGEMENT PRACTICES IN THE EVENT OF A DISEASE OUTBREAK:

- Where any lot of aquatic animals is shown to be infected with one or more of the diseases of concern listed in the Aquatic Organism Health Management Plan, all aquatic organisms on the premises must be quarantined or depopulated/destroyed.
- The waters that held the organisms will then be treated in a manner to destroy the infectious agent and then disposed of in an approved manner.
- The quarantined premises shall then be tested in a manner prescribed at appropriate intervals following disinfection for the presence of disease organisms. If the tests are negative, the premises shall be eligible for the release of quarantine.
- Except for diseases that are considered a hazard to the public, depopulation procedures for food fish will preferentially mean controlled slaughter and processing for food but will not include the rendering of product into feed for fish.

VIII. Mortality Removal/Disposal

The following practices are the acceptable sanitary methods for the removal of normal mortalities, inedible species or organisms unacceptable for any use.

AGRICULTURAL MANAGEMENT PRACTICES

- Sacrifice the organism, sanitize or disinfect and dispose of in accordance with local rules and regulations.
- Burial pits should be a reasonable distance from rearing units.
- Burial pits should provide enough depth to cover fish remains with several feet of soil and not leach into any waterway.
- Burial should not be within the range of mean high water table and at least two (2) feet deep so that agricultural practices are not disturbed.
- Quicklime should be spread over each layer of fish to disinfect and discourage scavengers such as birds and vermin.
- Contact the NJDA with any uncertainties or for questions on mass burials.
- Composting of diseased plants or animals should be done according to industry practices and should only be used when there is no danger of infection.

IX. Chemical and Drug Handling

The proper handling, application and disposal of chemicals and drugs through the use of AMPs can prevent the contamination of soil, surface waters, and ground water.

AGRICULTURAL MANAGEMENT PRACTICES (CHEMICAL AND DRUG USAGE AND HANDLING)

- Follow all product label directions for use, storage and disposal.
- Consult an aquatic organism health specialist or veterinarian prior to use of drugs.
- Use of therapeutic agents is limited to those permitted by the product label, with due recognition of species and culture conditions (temperature, feeding rates, water quality parameters) or as prescribed by a licensed veterinarian.
- Keep careful records of drug use and withdrawal status including: 1) diagnosis, 2) date and time of first dose, 3) name of drug or chemical, 4) rate/dose, 5) applicator (name of person), 6) date and time of last dose, and 7) withdrawal time of drug, 8) date product can be sold, 9) ID for animals treated.
- Observe appropriate withdrawal times.
- Dispose of drugs and containers in an appropriate, environmentally-sound manner by following label instructions for "hazardous materials."

AGRICULTURAL MANAGEMENT PRACTICES (SPILL MANAGEMENT)

- Contain spilling or leaking materials by utilizing barriers and/or absorbent material, as per the recommendations of the product label. Dispose of the contaminated material in conformity with the regulations applicable to the chemical nature of the agent.

X. Security and Biosecurity

In the event of an orange or red alert, many aquaculturists because of their dependence on water resources, are especially at risk. The following Agricultural Management Practices are designed to assist aquatic farmers prepare for possible emergencies. Some of the issues that should be considered including storage of chemicals and hazardous materials, mortality removal and disposal, health management are included in other AMPs. This set of AMPs focuses on additional security measures that may be implemented especially during orange and red alerts. Because each farm is unique, you should review these recommendations and determine which are appropriate for your facility.

AGRICULTURAL MANAGEMENT PRACTICES

General Security Procedures:

- Identify critical on-farm decision makers.

- Post contact information for police, fire and other emergency responders.
- Encourage staff to be alert to any signs of tampering or presence of unauthorized individuals.
- Identify any areas within your operation that are not secure and may be vulnerable to product adulteration/tampering.
- Immediately investigate any reports of suspicious activity and alert local law enforcement officials.
- Conduct daily security checks for signs of tampering or unusual situations.
- Restrict visitor access, require proof of identity, log in entries ***and exits.***
- Apply security procedures to ***every outside individual*** who enters your premises including government regulators, contractors, suppliers, couriers, reporters, etc.
- Accompany visitors at all times.
- Secure doors (including freight loading doors), windows and vents.
- Account for all keys.
- Stamp all keys with "Do Not Duplicate."
- Provide adequate interior and exterior lights.

Employees

- Screen all new hires and check immigration status when appropriate.
- Establish a system of positive identification such as a photo id.
- Collect identification badges when an employee is terminated either voluntarily or involuntarily.
- Be alert to unusual behavior.

Water Supply:

- Check the safety of your water source regularly and be alert to any changes in your results. Significant changes should be reported to local law enforcement.
- Maintain contact with public water supplier to be alerted to problems.
- Secure wells, pump houses or stations.
- Develop a system to close down intake pipes in the event of an upstream contaminant problem.

Finished Products

- Establish a recall procedure.
- Maintain records of customer contacts, addresses and phone numbers.
- Destroy any outdated or unusable labels.

XI. Marine Bivalve Facilities

AGRICULTURAL MANAGEMENT PRACTICES (FACILITY OPERATION):

- Facilities must be located, designed and operated in a manner that is consistent with applicable wetlands regulations.
- Seawater pumping, intake and discharge systems should be designed so that they do not impede natural circulation patterns, create currents that increase sedimentation, scouring, turbidity, navigation or damage the surrounding habitat.
- The farm is located and operated in conformity with provisions of shellfish sanitation regulations applicable to the particular phase(s) of production conducted.

AGRICULTURAL MANAGEMENT PRACTICES (SITE SELECTION):

- The facility must be located so that it minimizes environmental impacts and does not create an impediment to navigation.
- Facilities must meet all State building requirements, and local construction permits must be obtained prior to construction.

AGRICULTURAL MANAGEMENT PRACTICES (PIPE PLACEMENT):

- Pipes must be placed in a location and in a manner that minimizes environmental and aesthetic impacts.
- Discharge pipes must be situated to prevent excessive scouring of the bottom in the receiving waters.
- NJDEP Waterfront development permits may be required if any additional pipes are installed after receiving your Aquatic Farm License from the NJDA.

AGRICULTURAL MANAGEMENT PRACTICES (PUBLIC HEALTH PROTECTION):

- Follow all National Shellfish Sanitation Program criteria. For information on the criteria for this program, contact the New Jersey Dept. of Health and Senior Services.

AGRICULTURAL MANAGEMENT PRACTICES (DISEASE PREVENTION):

- Hatchery operators must maintain records of all broodstock purchases and seed sales for a period of two years. These records must be available for inspection by the NJDA upon request.

- Where applicable, the producer's license number must accompany bivalves being transported from a hatchery or nursery.

XII. Aquatic Plants

The use of noxious plants (weeds) as listed in "State & Federal Regulations" is not acceptable as a management practice. USDA APHIS (Animal and Plant Health Inspection Service) has regulations prohibiting the movement of listed noxious weeds (some of which are aquatic) into or through the U.S. without a federal permit. (http://www.aphis.usda.gov/permits/weeds/index.html)

AGRICULTURAL MANAGEMENT PRACTICES (FERTILIZER APPLICATION):

- If it is necessary to apply fertilizer into a grow-out tank or pond which is inundated, use fertilizer spikes that can be pushed into the substrate near the target plant. Once the "food spike" is below the surface, it should be covered with soil to help prevent the loss of nutrients to the water column.

- Apply fertilizer to substrate during preparation of the grow out tank while the tank is dry. Use a slow release fertilizer and evenly incorporate it into the soil.

- Minimize the need for additional fertilizer by maintaining a static water level in the production tanks or ponds.

XIII. Freshwater Finfish Culture

Fish such as trout, hybrid striped bass, and tilapia are some examples of fish that may be cultured in New Jersey. The list will continue to be updated as new aquaculture technologies emerge. Feed is a major input of pollution into any system. It is critical that feed be carefully monitored.

AGRICULTURAL MANAGEMENT PRACTICES

- Determine the amount of feed your system can handle while still maintaining healthy water quality conditions for the fish being cultured.

- Continually evaluate feed utilization and avoid overfeeding.

- Store feed correctly to preserve nutrient quality and avoid growth of mold and bacteria.

- Handle feed carefully to prevent the development of fine particles.

- Grade fish by size as frequently as possible for maximum growth and feed conversion.

- Maintain proper water quality parameters.

- Avoid overcrowding, overfeeding, and other stressors that may lead to lowered fish resistance and allow for pathogen intrusion.

- Maintain filter systems to avoid compromising water quality.

Aquatic Organism Health Management Plan (AOHMP)

Preventing Disease Introductions and Outbreaks in the New Jersey Aquaculture Industry

I. Introduction

Although aquatic organisms have been cultivated for centuries, intensive aquaculture production is a relatively new branch of agriculture. The USDA Census of Aquaculture, conveniently located on the worldwide web (*www.nass.usda.gov*), provides the most recent industry statistics for aquaculture production for a variety of organisms. With any type of live organism husbandry, there is a direct relationship between disease and production level. As the intensity of production increases, the prevalence of disease often increases. Intensification generally refers to increasing biomass per unit area. Biomass increases as the organisms grow or as the number of organisms increase.

The cumulative result on organisms of various insults and injuries is termed stress. The level of stress on an individual relates directly to husbandry practices, to water quality, and to physiologic condition and state of the individual. Stress has a significant impact on physiologic well-being. Disease incidence and severity are in many cases proportional to the amount of stress endured by a particular population. Stress is often a reflection of the quality of the environment and farm management with stress levels the greatest under poor environmental and/or management conditions. Strategies should be directed at minimizing disease transmission among cultured stocks, and from cultured stock to wild stock, and wild stock to cultured stock. When therapeutic agents or chemicals are needed as a treatment regime, they should be used in the most effective and controlled manner according to applicable state and federal laws and regulations.

Effective aquatic organism health management policies recognize the importance of disease prevention in preference to employing innovative diagnostics and treatment regimes. Five basic tenets required of aquatic organism health management are:

1. Water Quality
2. Quarantine
3. Nutrition
4. Disease diagnosis and treatment
5. Sanitation and disposal of wastes

With efficient aquatic organism health management, advances in technology can be better applied for disease prevention, diagnosis, and amelioration. The following Aquatic Organism Health Management Plan has been developed to minimize disease risks that may be detrimental to a new industry. This plan, which is embedded with the additional recommended AMPs, fulfills the following tasks:

1) Provides a proactive mechanism to predict and minimize disease outbreaks.

2) Benefits the aquaculturist and environment by protecting both aquacultured and wild stocks from major disease introductions into the State of New Jersey and develops means to confine disease outbreaks if they occur.

3) Suggests a mechanism for establishing export inspection protocols that will help assure buyers of the quality and safety of locally farm-raised products thereby expanding available markets for New Jersey producers.

4) Establishes a standing aquaculture technical committee to deal with emergency disease situations in a practical, reasonable and timely manner.

5) Provides feedback to growers on disease issues in order to facilitate better disease management based on locally, regionally and nationally reported disease outbreaks.

6) Addresses and decreases stress on cultured organisms with appropriate agricultural management practices.

II. Aquatic Organism Pathogens or Disease

Proactive measures for disease diagnosis and containment

Disease diagnosis and containment are intimately linked with several factors that include disease expertise available in a particular state, the severity and infectivity of the pathogen or disease-causing agent, geographical and historical information, and the species infected.

In order to understand disease risks and make appropriate risk assessments for newly introduced pathogens in New Jersey, the Department of Agriculture and the Department of Environmental Protection will work in collaboration to monitor the species of aquatic organisms present in the State and known pathogens that can infect them.

A. Monitoring

Both the New Jersey Department of Agriculture and the Department of Environmental Protection will monitor for specific pathogens at their discretion.

B. Disease Transmission.

Disease is often the result of a breach in husbandry practices that sometimes are unpredictable or unavoidable. Examples of some potential origins for disease outbreaks include producers/suppliers inside or outside the State, birds, other predators, wild fish, transport trucks, water supply, farm practices, feed, ship ballast, humans or flood. Risks should be evaluated regarding importing frozen and live products from other countries or states, where potential pathogens exist, especially if these products are used as food sources for, or come in contact with, other aquaculture species.

Diseases can and will occur even on well-managed farms. Many disease organisms occur throughout the Atlantic States region based on climatic and geographic factors. Because of difficulties in regulating transfer of water and aquatic organisms, all states should plan for the occurrence of a variety of diseases and develop strategies to contain outbreaks of diseases listed as potential threats in each state. These strategies should include aquatic organism health management practices and incorporate means for risk analysis, so actions can be taken in an outbreak to prevent further transmission of the disease(s) to other stocks and populations.

Sometimes the only way to detect diseased animals is through analyzing production data as well as performing laboratory testing. Increased productivity can be achieved by identifying and understanding disease. The

costs of disease for a producer include: 1) actual loss of organisms, 2) loss of production (e.g. decreased weight gain), and 3) costs of control or prevention. Diseases can be infectious or non-infectious. Infectious diseases are caused by different pathogens that may readily transfer from one organism to another. This category causes the greatest threat to both aquaculture-reared and wild finfish and shellfish. Some of the pathogens that can cause disease include viruses, bacteria, protozoans, and metazoans. Non-infectious diseases are diseases that cannot be transferred directly from organism to organism. Other factors that can lead to lost production include: 1) poor diet, 2) toxins, and 3) poor water quality.

Trained specialists or aquatic health professionals can often accurately trace even the most covert disease organisms after many hours of diligent laboratory testing and thorough investigation. This work can then provide valuable information to the growers. Diseases can and will occur on even well managed farms and this chapter plans to aid with identifying these problems and preventing future outbreaks. The Department of Agriculture hopes to assist aquaculturists as disease problems emerge.

III. Disease Classification System

Generally the same infectious disease organisms are found throughout the world and occur in certain locations based on climatic and geographic factors. Because of difficulties in regulating transfer of water, animals and plants, all countries should plan for the occurrence of a variety of diseases. This classification system simplifies disease concerns for aquatic animals in the State of New Jersey. In this section are tables outlining pathogens that have red or yellow classification only. Appendix A contains a more comprehensive chart with several disease examples. Specific AMPs can be found in the sections on "Treatment/Control," "Hatchery Certification/Inspection," and "Comments/NJ History/Transport." The following points are criteria established for disease classification.

1) Geographical presence or absence in North America and for each state
2) Availability of accurate diagnostic tests
3) Availability of treatments for the disease in question
4) Pathogenicity and virulence of pathogen
5) Reviewed scientific literature of the nature of the pathogen and its prevalence in wild fisheries within the state and in state boundary waters
6) Species of organisms at risk
7) Most current information in regional, national, and international databases for existing and potential or newly appearing pathogens

- **Red Light Diseases** are diseases that require immediate reporting to the Department of Agriculture and State Veterinarian. They demand immediate action for containment and may necessitate stock destruction. No animals originating outside the State having these diseases will be permitted in the State. These diseases may fit into one or more of the following categories: 1) have not been found recently in the State, 2) have no known treatment, 3) pose a significant threat to native fisheries, and 4) can cause significant to catastrophic losses.

- **Yellow Light Diseases** also require reporting to the Department of Agriculture and State Veterinarian. They may require action for containment. Aquatic organisms originating outside the State having tested positive for these diseases may not be permitted for import unless otherwise specified by the Departments of Agriculture and Environmental Protection. These diseases: 1) may or may not have been found in New Jersey, 2) have limited effective treatments, 3) may cause significant losses, and 4) pose a potential threat to native fisheries.

- **Green Light Diseases** do not require reporting to the state, but may require specialist assistance from an aquatic health professional for control and treatment. Although no pathogens are good, these diseases/parasites: 1) are ubiquitous in native waters and wild stocks, 2) cause moderate to low mortality rates, and 3) often have known treatments.

If not managed correctly all pathogens have the potential to cause serious losses on farms.

Tables 1 and 2. Lists of pathogens separated according to this classification scheme are found in **Table 1** for finfish and **Table 2** for invertebrates. All diseases classified as red are pathogens recognized as reportable to the Office Internationale des Epizooties (OIE) and testing is required prior to export from the United States.

Red Light Diseases	Yellow Light Diseases	Green Light Diseases
Epizootic Hematopoietic Necrosis (EHN)	Infectious Pancreatic Necrosis Virus (IPN)	Koi Ulcer Disease: *Aeromonas hydrophila*
Infectious Hematopoietic Necrosis Virus (IHN)	Furunculosis: *Aeromonas salmonicida* (BF)	Columnaris: *Cytophaga columnaris*
Viral Hemorrhagic Septicemia Virus (VHS)	Bacterial Kidney Disease: *Renibacterium salmoninarum* (BKD)	Bacterial Gill Disease : *Flavobacterium branchophilum* (BGD)
Proliferative Kidney Disease (PKD)	Viral Encephalopathy and Retinopathy	Endemic Protozoan and Metazoan Parasites
Enteric Redmouth: *Yersinia ruckeri* (BR)	*Pleistophora ovariae* in baitfish	
Oncorhynchus Masou Virus disease (OMVD)	*Streptococcus iniae* and other species	
Asian Tapeworm: *Bothriocephalus acheilognathi*	Channel Catfish Virus (CCV)	
Spring Viremia of Carp (SVC)	Enteric Septicemia of catfish: *Edwardsiella ictalari* (ESC)	
Koi Herpes Virus (Newly emerging Disease)	Edwardsiella Septicemia: *Edwardsiella tarda*	
Whirling Disease *Myxobolus cerebralis*	Non-endemic Protozoan and Metazoan Parasites	

As new disease outbreaks occur and previously undescribed pathogens cause problems, this list will be modified and adjusted. It must also be noted that all states have different importation requirements. Specific pathogen testing for export of aquatic or organisms from New Jersey may require additional testing. In Appendix A, more elaborate information is found on these and other parasites. The finfish section is arranged with the following categories:

- **Pathogen/Disease:** Known pathogen and/or the specific disease it may cause.
- **Classification:** Classification for these pathogens follows the red, yellow, green light strategy used above.
- **Species Affected:** Lists species known to be susceptible to the disease.
- **Known Geographic Range:** Lists areas where the disease has been reported. This is a cautionary note that should be considered when importing finfish from that area.
- **Sampling/diagnosis:** This category lists the diagnostic protocol for the specific pathogen.
- **Treatment /Control:** When appropriate, this category lists known treatment or means to avoid infection from the specific pathogen.
- **Policy Regarding Release into Freshwater in New Jersey:** Explains the policy for release.
- **Recommendations for Aquaculture:** This lists additional comments pertaining to specific pathogens, historical information regarding these pathogens in New Jersey, and remarks about transporting infected eggs or organisms with such pathogens.

Overviews of the OIE disease testing requirements are provided in Appendix B to provide producers information for international export.

Table 2 lists some of the potential threats to the shellfish industry. Diseases that must be tested for prior to export from the United States, which are considered reportable or significant by the OIE, are found in Appendix B.

Table 2. Shellfish Pathogens

Red Light Diseases/Parasites Molluscs	Yellow Light Diseases/Parasites Molluscs	Green Light Diseases/Parasites Molluscs
Perkinsus chesapeaki	Juvenile Oyster Disease (JOD)	Quahog Parasite X (QPX) (Protist)
	Disseminated neoplasia blue mussel	*Perkinsus marinus* (Dermo)(Protist)
		Chlamydia-Rickettsia Disease
		Hexamita sp.
Crustacea	Crustacea	*Nematopsis ostrearum*
Baculovirus pennaei	Yellowhead Disease	*Pseudoklossia* sp. (Kidney Coccidia)
Baculoviris species		
White Spot Disease Virus		
Taura Virus		

As new disease outbreaks occur and previously undescribed pathogens cause problems, these lists will be modified and adjusted. It also must be noted that all states have different importation requirements and specific pathogen testing for export of aquatic organisms from New Jersey may require additional testing. In Appendix A, more detailed information is found on these and other pathogens. The shellfish section is arranged with the following categories:

- **Pathogen/Disease:** Known pathogen and/or the specific disease it may cause. Shellfish pathogens are listed under that species of aquatic organism most likely infected.

- **Classification:** Classification for these pathogens follows the red, yellow, green light strategy used above.

- **Sampling time/diagnosis:** This category lists the seasonal pattern for the specific pathogen and type of diagnostics used.

- **Treatment/Control:** When appropriate, this category lists known treatment or means to avoid infection from the specific pathogen.

- **Hatchery Certification/Inspection:** This list indicates whether hatcheries need to be certified or inspected, and if so, suggests protocols to monitor or inspect for specific pathogens.

- **Comments/NJ History/Transport:** This lists additional comments pertaining to specific pathogens, historical information regarding these parasites in New Jersey, and remarks about transporting infected eggs, larvae, or organisms with such pathogens.

Overviews of the OIE disease testing requirements are provided in Appendix B to provide producers information for international export.

IV. Reporting Aquatic Animal Diseases

A. Notice of Existence of Dangerous Diseases (N.J.S.A. 4:5-4)

Any veterinarian or other person (including but not limited to any auctioneer, broker, dealer, aquaculturist, extension agent, etc.) who shall gain knowledge of the existence or suspected existence of red or yellow light diseases within the State shall notify the Department of Agriculture without delay, and in any case within 48 hours. Upon such notification, the NJDA will promptly notify the Division of Fish & Wildlife in NJDEP. These lists are subject to change as new information is developed by federal and State agencies. Appendix A provides valuable additional information for diseases of aquatic organisms.

B. Quarantine of Aquatic Organisms and Premises (N.J.S.A. 4:5-1, 4:7-1)

Upon receiving information that an infectious or contagious disease exists or is suspected to exist in any aquaculture facility, the Department of Agriculture may investigate or cause an investigation to be made. If the Department deems it to be advisable it may quarantine such aquatic organisms, and take precautionary measures with relation to other animals exposed to the disease as shall be deemed necessary.

a). After reporting and confirmation by the Department of Agriculture or individuals working directly under the Department of Agriculture, that any aquatic organism has been infected by a red or yellow classified disease or has been exposed to such classified disease organisms, the aquatic organisms may be subject to quarantine on farm or at a designated place established by the Department of Agriculture. Quarantined shellfish may not be moved. This provision may prevent the introduction of potentially infected or infectious aquatic organisms into an area or body of water where they are not present. The quarantined area will be strictly closed to any subsequent shipments of aquatic organisms and no water will be released from the quarantine facility without written permission of the State Veterinarian. Quarantines will be terminated when and if subsequent diagnostic tests and procedures required by the Department of Agriculture confirm that the aquatic organisms are no longer infected and the premises are no longer contaminated. **(N.J.S.A. 4:5-16)**

b). The Department of Agriculture reserves the right to oversee disinfection of farms, trucks, markets, auctions and all premises that may have been contaminated due to an outbreak of infectious disease.

c). Where hatcheries are involved, the entire establishment or a portion thereof shall be quarantined at the discretion of the State Veterinarian.

d). In some disease outbreaks the Department of Agriculture reserves the right to ban the movement and sale of any or all aquatic organisms and/or aquatic organism products in certain geographical regions that may include an individual farm, county, and/or the entire State. **(N.J.S.A. 4:5-8)**

1. Handling Aquatic Organisms and Premises Confirmed to be Infected with red or yellow listed diseases:

   The Department of Agriculture reserves the right to depopulate as a disease control method if aquatic organisms or eggs are infected or potentially infected with one or more of the red and/or yellow classified disease organisms. Depopulating, disinfecting, water sterilization and subsequent disease monitoring will be done in a manner approved by the Department of Agriculture. This will extend to hatcheries as well. (**N.J.S.A. 4:5-10**)

2. Immediate Processing of Infected Aquatic Organisms

In certain disease outbreaks the Department of Agriculture has the right to grant permission for immediate processing, allowing marketing of certain infected/potentially infected aquatic organisms. For shellfish planted in open water, the feasibility and efficacy of the methods employed to execute the recovery of the crop shall be determined by the Aquaculture Technical Committee. All the precautions and disinfection procedures mandated by the Department of Agriculture in disease outbreak situations apply to all areas potentially contaminated by these aquatic organisms.

C. Indemnification (N.J.S.A. 4:5-10)

The Division of Animal Health shall have the authority to destroy or order to be processed any animals it deems necessary to prevent the spread of the diseases that threaten the viability of the industry. For each organism processed to prevent the spread of disease, the owner shall receive the net proceeds, if any, of the sale of the animal and in addition, if funds are available, shall be paid a compensatory indemnity, the total of sales proceeds and indemnity not to exceed the market value of the animal.

V. Records of Aquatic Organisms

A. Contents of Record

To protect their stock and investment, it is strongly encouraged that aquaculturists keep careful records.

The record should include:

i. Identification number of group or lot of aquatic organisms and approximate number of organisms per group;

ii. The name and address of the person from whom purchased or if purchased at a commission sale the name and address of the dealer;

iii. The name and address of the person from whom the aquatic organisms may have been held for more than 24 hours prior to transport;

iv. The name of the person to whom sold or exchanged;

v. The date the aquatic organisms were purchased and date the aquatic organisms were sold;

vi. Species and size/life stage (i.e. fingerling) of aquatic organisms purchased in each group.

B. When Records Should Be Made

(a) When aquatic organisms are purchased or exchanged, the required information relating to such transaction shall be recorded immediately upon completion of the transaction.

(b) When the aquatic organisms are sold, the required information relating to the sale or exchange shall be recorded immediately upon completion of that transaction.

VI. Aquatic Organism Importation

A. Import Permit

A person may not import any aquatic organism into New Jersey for the purposes of aquaculture without a valid New Jersey Aquatic Organism Importation Permit in his or her possession. Application for a New Jersey Aquatic Organism Importation Permit must be made in writing on a form available from the Office of Aquaculture Coordination, Department of Agriculture, P.O. Box 330, Trenton, N.J. 08625.

B. Health Certification (N.J.A.C. 2:3-1.1)

All shipments of aquatic organisms into the State for the purposes of aquaculture should be accompanied by documentation from point of origin that includes species, health history, and the name and address of the original source. It should also include the name and address of additional premises if the shipment was held there for more than a twenty-four hour period. Health certificates must be completed by a licensed veterinarian or other individual authorized by the appropriate state/country of export government agency. If a shipment will not be accompanied by a health certificate, written authorization must be obtained from the New Jersey State Veterinarian.

1. Contents of Certificate of Veterinary Inspection or Health Certificate. (N.J.A.C. 2:3-1.2)

(a) The official Certificate shall indicate that the aquatic organisms designated thereon comply with all requirements for entry into New Jersey.
(b) The official Certificate shall include a legible report of the following:
    1. Complete name and address of consignor;
    2. Origin of the aquatic organisms;
    3. Complete name and address of consignee;
    4. Destination of the aquatic organisms;
    5. Description of the aquatic organisms which shall include species, number and age of the animals;
    6. A statement that the examining veterinarian or pathologist personally inspected the animals described and found them free from symptoms of particular infectious, contagious, or communicable disease or known exposure thereto within 30 days of shipment by using **AFS Blue Book** inspection procedures.

2. Copy of Certificate to New Jersey Department of Agriculture. (N.J.A.C. 2:3-1.3)

A copy of the official Certificate shall be mailed promptly to the New Jersey Department of Agriculture, Division of Animal Health, PO Box 330, Trenton, New Jersey 08625-0330.

3. Expiration date of Certificates. Official Certificates shall be void 30 days after issuance. (N.J.A.C. 2:3-1.4)

C. Quarantine of Aquatic Organisms Entering State (N.J.A.C. 2:3-1.5)

All aquatic organisms entering the State may be subject to quarantine by the New Jersey Department of Agriculture.

D. Importing Diseased Aquatic Organisms (N.J.A.C. 2:3-1.6)

Aquatic organisms from facilities under quarantine because of any infectious, contagious, or communicable disease, or currently classified as suspected to harbor or be the source of any infectious, contagious, or communicable disease shall not be imported into the State unless prior approval is granted by NJDA and NJDEP.

E. Failure to Meet Importation Requirements (N.J.A.C. 2:3-1.8)

Aquatic organisms not meeting these requirements may be refused entry into the State, or if already in the State, shall be placed under quarantine until processed, returned to State or country of origin, or disposed of in accordance with decision of the New Jersey Department of Agriculture.

F. Agencies that Regulate the Trade and Transport of Aquatic Organisms

Nationally, the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) has established guidelines for inspecting aquaculture facilities and is developing procedures for aquaculture certification. There are several USDA certified fish diagnostic centers throughout the United States. Individual laboratories are certified for specific diseases. The two laboratories closest to New Jersey are:

Maryland Fish Health Diagnostic Laboratory
Department of Agriculture
8074 Greenmead Drive
College Park, MD 20740
Phone: (301) 935-6074

Infectious hematopoietic necrosis virus
Infectious pancreatic necrosis virus
Viral hemorrhagic septicemia virus
Oncorhynchus masou virus
Renibacterium salmonarum
Aeromonas salmonicida
Yersinia ruckeri
Myxobolus cerebralis
Ceratomyxa shasta

Pennsylvania Animal Diagnostic Laboratory System
State Veterinary Laboratory
Harrisburg, PA
Phone: (717) 787-8808

Infectious hematopoietic necrosis virus
Infectious pancreatic necrosis virus
Viral hemorrhagic septicema virus
Spring viremia of carp virus
Renibacterium salmonarum

Aeromonas salmonicida
Yersinia ruckeri
Myxobolus cerebralis
Ceratomyxa shasta
Gyrodactylus spp.

Other certified diagnostic laboratories can be found at the following website: *www.aphis.usda.gov/vs/nvsl/*

Shellfish Labs

Dr. Susan Ford
Haskin Shellfish Research Laboratory
Rutgers University
6959 Miller Avenue
Port Norris, NJ 08349
(856) 785 - 0074

Dr. Eugene Burreson
Virginia Institute of Marine Science
College of William and Mary
Gloucester Point, VA 23062
(804) 684 - 7108

Dr. Roxanna Smolowitz, Veterinary Pathologist
Marine Biological Laboratory
7 MBL St.
Woods Hole, MA 02543
(508) 289 - 7400

Paul S. Sarbanes Cooperative Oxford Laboratory
Maryland Department of Natural Resources
Oxford, Maryland
(410) 226-5193

Internationally, the *Office International Des Epizooties* (OIE) has developed an International Aquatic Animal Health Code and Diagnostic Manual for Aquatic Animal Diseases.

VII. AMPS for Therapeutic and Biological Agent Use in Aquaculture

Sometimes drugs, antibiotics, vaccines, or chemicals are needed for the prevention or control of disease. Currently few products are available for aquaculture producers. The use of these agents, their storage and their disposal should be done in accordance with state and federal laws as outlined by the manufacturers guidelines as appears on the product label and appropriate regulating agencies. These agents should be used only under qualified supervision. Any off-label usage of these agents can only be prescribed by a licensed veterinarian. To ensure antibiotic efficacy for both human and aquaculture disease treatment, prophylactic or low dose antibiotic administration should be avoided.

Certain agents are not regulated or are considered low priority therapeutic additions in the United States. Low regulatory priority drugs include salt, acetic acid, ice, garlic, hydrogen peroxide, etc. A complete list of low

regulatory drugs is available at Appendix C. Regulations are constantly changing in the area of biological and therapeutic usage. Consult the FDA Center for Veterinary Medicine's Aquaculture website for the latest information on drug use in aquaculture *http://www.fda.gov/cvm/index/aquaculture/antibiotic.htm.*

The use of therapeutic and biological agents in aquaculture can be reduced through effective health management. A direct result of proper stress management in aquaculture practices can be a decreased need for therapeutic and chemical interventions with an increase in profit. Before application of any products for disease control, a proper diagnosis should be obtained. This will help ensure that the appropriate therapeutic agents are used and will minimize environmental exposure to potential chemical threats.

In addition to the potential effects of therapeutic and biological agents, use of pesticides, herbicides, disinfectants, and toxicants near aquaculture facilities and ponds may have deleterious effects on fish viability and quality. This may involve current or previous agricultural and industrial uses unrelated to aquaculture. The Department of Agriculture may elect at any time to work with the NJ DEP or federal agencies to establish routine monitoring for specific agents in environmentally sensitive areas.

All regulations regarding therapeutic agents and use of biologics are federally mandated. As an example, several agencies in the United States currently regulate various agents.

Currently:

The United States Department of Agriculture (USDA) regulates vaccines and veterinary biologics (bacterins, antisera, diagnostic kits and other products of biological origin). The Center for Veterinary Biologics certifies that the veterinary biologics available for diagnosis, prevention and treatment of animal diseases are pure, safe, potent and effective. *www.USDA.gov*

The Food and Drug Administration (FDA) regulates drug usage in aquaculture facilities. Their website *www.FDA.gov* includes extensive and useful information on this subject.

The Environmental Protection Agency (EPA) regulates pesticide usage. *www.EPA.gov*

In the United States, a licensed veterinarian is required to prescribe most therapeutic agents. When no approved treatment exists for various diseases or treatment is not specified by the product label, the "extra-label" use of these products can be prescribed only by a licensed veterinarian under conditions stipulated by the FDA. This veterinarian accepts responsibility for the administration, withdrawal times, and subsequent consequences. "Extra-label" usage of agents not prescribed or used under supervision of a licensed veterinarian or applied in feeds is illegal in the United States.

Before application, the aquaculturist should understand labeling, approval, application, storage, and disposal for any treatment products. Withdrawal times for all federally approved medications must be strictly observed before aquatic organisms can be harvested for human consumption. Detailed records for use of these agents, which may include, but is not limited to, date, agent, dosage, length of treatment, withdrawal time, and systems treated must be included for every system treated. Additional information on approved drugs for aquatic organisms raised for human consumption is contained in Appendix C.

VIII. Aquaculture Technical Committee

A. A special Committee has been established by the Department of Agriculture to address technical problems that may arise in such areas as species importation and health, among others.

B. The Committee should be readily available to address emergency situations and recommend a course of action to the Department of Agriculture, Department of Health and Senior Services and the Department of Environmental Protection.

C. The Committee shall include but may not be limited to:

- A representative from the NJ Department of Agriculture
- Two Aquatic Animal Health Specialists from the State (shellfish and finfish specialists)
- New Jersey State Veterinarian
- When applicable: Owner/Operator of any facility in question
- 2 Representatives from the aquaculture industry (Finfish and Shellfish)
- Rep. from Department of Health and Senior Services
- 2 representatives from NJDEP at least one of whom shall represent the Division of Fish and Wildlife
- A representative of NJDA Division of Plant Industry when appropriate

D. The responsibilities of the committee are as follows:

1. The committee shall convene immediately when an exotic pathogen has been detected, evaluate the situation, develop a contingency plan, and recommend a course of action to the New Jersey Department of Agriculture.

2. The committee shall have the responsibility of advising on the containment, seizure, and destruction of stock to prevent further spread of diseased species into natural waters and oversee actions approved by the Department of Agriculture.

E. The committee will meet annually to discuss aquatic organism health issues and provide a summary of that meeting to the Aquaculture Advisory Council.

F. The Committee shall address, but not be limited to, the following matters:

1. Review Emergency procedures enacted by the committee and develop plans to address future emergencies.

2. Review pathogen classification and new disease data recorded by the State Veterinarian and Aquatic Health diagnosticians to address emerging pathogen concerns.

3. Review protocols and address technical issues for disease diagnostic and water quality procedures.

4. Make recommendations regarding species newly introduced or proposed for introduction for aquaculture purposes.

5. Provide a means to disseminate information to New Jersey producers to encourage proactive responses to disease problems and potential threats to Aquatic Organism Health.

IX. Abbreviations:

BKD Bacterial Kidney Disease (*Renibacterium salmoninarum)*

CCV Channel Catfish Virus

CS Ceratomyxosis (*Ceratomyxa shasta*)

Dermo *Perkinsus marinus*

ERM Enteric Redmouth

Furunc Furunculosis (*Aeromonas salmonicida*)

IHN Infectious Hematopoietic Necrosis Virus

IPN Infectious Pancreatic Necrosis Virus

JOD Juvenile Oyster Disease

MSX *Haplosporidium nelsoni*

OMDV *Oncorhynchus masou* Virus

PKD Proliferative Kidney Disease

QPX Quahog Parasite X

SSO *Haplosporidium costale*

VHS Viral Hemorraghic Septicemia Virus

WD Whirling Disease (*Myxobolus cerebralis)*

X. Definitions:

Agricultural or horticultural purposes (or agricultural or horticultural use) – any production of plants or animals useful to man, including but not limited to: forages or sod crops; grains and feed crops; dairy animals and dairy products; poultry and poultry products; livestock, including beef cattle, sheep, swine, horses, ponies, mules or goats, and including the breeding and grazing of any or all of such animals; bees and apiary products; fur animals; aquatic organisms as part of aquaculture; trees and forest products; fruits of all kinds, including grapes, nuts, and berries; vegetables; nursery, floral, ornamental and greenhouse products; or any land devoted to and meeting the requirements and qualifications for payments or other compensation pursuant to a soil conservation program under an agency of the Federal Government.

Applicant – a person who is in or is seeking to enter into the aquaculture industry and who submits an application for a license to the NJDA.

Approved laboratory methods – methods described in the latest edition of the "Procedures for the Detection and Identification of Certain Fish Pathogens" published by the American Fisheries Society Fish Health Section known as the Fish Health Blue Book.

Aquaculture – means the propagation, rearing and subsequent harvesting of aquatic organisms in controlled or selected environments, and the subsequent processing, packaging and marketing, and shall include, but need not be limited to activities to intervene in the rearing process to increase production such as stocking, feeding, transplanting and providing for protection from predators.

Aquaculture Advisory Council – the Aquaculture Advisory Council established by the New Jersey Aquaculture Development Act.

Aquaculture therapeutics – drugs, medications, and disease control chemicals that are approved for aquaculture use by the United States Food and Drug Administration.

Aquaculturist – (1) a person engaging in aquaculture. (2) An individual, partnership, or corporation involved in the production of cultured aquatic stock or parts thereof.

Aquarium facilities – facilities that rear or hold private aquatic life for sale for aquarium or display purposes.

Aquatic farm – (1) a licensed facility used for hatching, raising, rearing, and culturing private aquatic life in waters and preparing aquatic life for sale, including, but not limited to, ponds, vats, tanks, raceways, and other indoor and outdoor facilities that an aquatic farmer owns or waters of which an aquatic farmer has the use. (2) any water system and associated infrastructures capable of holding and/or producing cultured aquatic stock. It may also refer to a co-located facility and may include both hatchery and grow-out components, multi-species farms, processing, packaging, and marketing.

Aquatic organism – (1) any marine, estuarine, diadromous, or freshwater animal or plant with the exception of mammals and birds. (2) any plant or animal that grows or lives in or upon the water. (3) an animal or plant of any species or hybrid thereof and includes gametes, seeds, eggs, sperm, larvae, juvenile and adult stages any of which is required to be in water during that stage of its life.

Broodstock – (1) sexually mature organisms capable of producing gametes. (2) sexually mature organisms capable of potentially producing gametes (e.g., in the case of bivalves, "broodstock" often includes individuals

that are not reproductively competent during most of their sojourn in a controlled or natural system). (3) sexually mature aquatic organisms, either domesticated or wild, used to propagate cultured aquatic stock.

Certification/certified – meeting the agreed criteria for a program or regulatory standard.

Closed system – an aquaculture facility or system with discharges that do not connect in any way to the waters of the State prior to the effluent being subject to filtration or percolation designed to prevent cultured aquatic stock from escaping, and which generally recirculates its system process wastes.

Commissioner – (1) the Commissioner of the Department of Environmental Protection or his or her designee.

Containment facility – a facility that: 1) does not discharge to public waters or to waters of the State directly connected to public waters; 2) raises aquatic life that is not released directly into the wild.

Culture facility – an establishment where aquatic organisms are grown for sale or for release into coastal and inland waters.

Cultured aquatic stock – privately owned aquatic organisms lawfully acquired, held, and grown in a licensed facility.

Discharge – an intentional or unintentional action or omission resulting in the releasing, spilling, leaking, pumping, pouring, emitting, emptying, or dumping of an effluent.

Disease – (1) functional and/or anatomic abnormalities in a population or the body of an individual caused by any environmental condition, infectious or noninfectious. Clinical disease is detectable by one or more of a person's senses. Sub-clinical disease is detectable only by selected laboratory tests or diagnostic aids. The detection of a potential pathogen does not constitute the detection of disease. (2) an interruption, cessation, or disorder of bodily functions, systems, or organs.

Emergency enzootic disease area – an enzootic disease area that harbors an emergency aquatic organism disease. Trout, salmon, or catfish species are from an emergency enzootic disease area only if the individual species in question can carry one or more of the emergency disease pathogens present.

Emergency aquatic disease – designated aquatic disease agents not already present in this State that could impact populations of aquatic life if inadvertently released by infected aquatic life, including channel catfish virus, viral hemorrhagic septicemia virus, infectious hematopoietic necrosis virus, infectious pancreatic necrosis virus, whirling disease, ceratomyxosis, proliferative kidney disease, and epizootic epitheliotropic virus disease.

Enzootic – a disease (often of low prevalence and/or low individual infection intensity) which is constantly present in a population.

Enzootic disease area – an area with well-defined geographic boundaries which harbors one or more recognized disease pathogens.

Epidemiology/Epizootiology – the quantitative and/or descriptive study of the frequency, distribution, and determinants of health and disease in populations.

Epizootic – an outbreak of a disease in which there is an unusually large number of cases. A disease or phase of disease of high morbidity, and one that is only irregularly present in recognizable (clinically patent) form.

Eradication – disease management strategy whereby efforts are made to eliminate the pathogen from a defined population or geographic region.

Etiologic agent – the causative agent of a disease.

Exhibition – displaying or showing aquatic animals for competition or the advancement of the species, or for sale where multiple sellers are present with their aquatic animals and may include among other examples, fairs, farm shows, breeding shows, sales, and swap meets.

Exotic – those organisms that have not been recognized to be present in New Jersey as of the effective date of implementation of regulations originating from these guidelines.

Finfish – (1) true fish which are any number of strictly aquatic craniate vertebrates that include the teleosts, elasmobranches, and cyclostomes. These fish typically have an elongated, spindle-shaped body terminating in a caudal fin. (2) live fish, fish eggs, or fish gametes, but not to include aquarium fishes and ornamental fishes kept in closed containers.

Fish Health Blue Book – the standardized set of procedures and guidelines established and published by the American Fisheries Society Fish Health Section for the detection and identification of fish and shellfish pathogens.

Fish health inspection – an on-site, statistically based sampling in accordance with processes in the Fish Health Blue Book for all lots of fish in a facility. The inspection must include at least viral testing of ovarian fluids at the 95 percent confidence level of detecting two percent prevalence of disease (ovarian fluids must be sampled for certification of viral hemorrhagic septicemia and infectious hematopoietic necrosis). Bacterial diseases must be sampled at the 95 percent confidence level of detecting a five percent prevalence of disease. The inspection must be performed by a fish health inspector in cooperation with the producer with subsequent examination of the collected tissues and fluids for the detection of certifiable diseases.

Gametes – haploid reproductive cells or nuclei, the fusion of which during fertilization leads to the formation of a zygote.

Genetically altered – transgenic organism created by recombinant DNA technology.

Hatchery – incubators, hatchers, and auxiliary equipment on one premises operated for the purpose of hatching or incubation of hatching eggs and rearing to settlement in the case of molluscs.

Hatching eggs – fertile eggs used to produce embryonated eggs, or aquatic animals.

Hazard – elements or events that pose potential harm; biological or chemical agents with the potential to cause an adverse health effect.

Hybrid – organism resulting from genetic combinations of two or more species or intraspecific genetic combinations (i.e., crosses among different strains of the same species).

Import – to transport or receive aquatic organisms from outside the jurisdiction of New Jersey and intentionally place said organisms in the waters of the State or into any aquacultural system with a discharge into the waters of the State.

Incidence – (1) a rate of disease describing the probability of a new disease case developing during a defined time interval. Crude true incidence (I) is calculated from the proportion of animals developing disease (D) during a defined time period (T) from the average population (N) at risk during that time period (I=D/N/T). (2) the number of new cases of a particular disease within a given period of time, and within the particular population being studied or described. Synonymous with "cause-specific morbidity."

Indigenous – those live organisms currently recognized to occur in the State of New Jersey.

Infected animal – an animal whose body has been invaded by a disease-causing agent and from whose body that agent may be recovered.

Infection – the introduction or entry of a pathogenic organism or virus into a susceptible host whether or not this causes detectable pathologic effects (overt disease).

Intensive culture – the rearing of organisms at densities greater than can typically be supported in the natural environment.

Introduce – the intentional or accidental release of any non-native aquatic organisms or the pests, and pathogens of any aquatic organisms into the waters of the State as a result of their importation or subsequent aquacultural activities.

Laboratory – any laboratory operating in or out of the State, capable of conducting differential diagnostic tests for aquatic animal diseases.

Lethal dose – the amount of toxin that results in the death of an individual organism most often expressed as the amount that results in the death of a defined fraction of a population that has been exposed equally to that dose; e.g., an LD_{50} is the dose level that will kill 50% of an exposed population under the conditions of "exposing" or "treating" a population of a sufficient size that will permit a statistically valid estimation of this parameter.

Licensed facility – a licensed aquatic farm, including all licensed waters.

Lot – a group of fish of the same species and age that originated from the same discrete spawning population and that always have shared a common water supply, or various age groups of adult brood stock of the same species that have shared the same containers for one brood cycle.

Metazoan – multi-cellular animal.

Morbidity – the state of being diseased or infected.

Native species – any species of any plant or animal that naturally occurs in the waters of the State.

Naturalized species – any species or hybrid thereof of any aquatic organism which has been introduced to the waters of this State and has become established by reproducing in the waters of this State.

NJDEP – the New Jersey Department of Environmental Protection.

Non-native species – any species of plant or animal that does not occur naturally in the waters of the State.

Open system – an aquaculture facility with a water discharge(s) that connects to the waters of this State without being screened, filtered, or percolated prior to discharge to prevent cultured aquatic stock from escaping.

Opportunist – an organism that typically has low invasivity or virulence in a particular host, but which can establish a pathogenic or disease causing relationship under certain stress conditions for the normally resistant host.

Ornamental species – any aquatic organism kept primarily for its aesthetic value which can be propagated in open-air facilities within this State under normal circumstances.

Pathogen – a specific cause of disease. A microorganism capable of producing disease.

Pathogenicity – the ability of an agent to cause a certain phase specific disease in a host, usually understood to be referenced to the normal state of host resistance, and which rarely exists in close proximity to the host without eliciting the disease state, whether clinically patent or not.

Pollutant – any dredged spoil, solid waste, incinerator residue, sewage, garbage, refuse, oil, nutrient, grease, sewage sludge, munitions, chemical wastes, biological materials, wrecked or discarded materials, radioactive substance, thermal waste, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal, or agricultural waste or other residue discharged into the waters of the State. "Pollutant" includes both hazardous and non-hazardous materials.

Prevalence – the proportion of organisms determined to be infected by a particular agent among all those examined at a particular time.

Prevention – disease management strategy designed to exclude disease from a population or a defined geographic area.

Protist – a unicellular organism including protozoans, certain fungi, slime molds and algae.

Protozoan – unicellular organism.

Quarantine – the confinement of aquatic organisms, including the existing and subsequent seeds, offspring and/or eggs, to a specific premises at a specific location for a specific time. It may include an entire facility or an entire business establishment, including multiple sites, or it may only include a portion thereof. It may also involve effluent water and wastes or sludge, and equipment, hauling trucks, harvesting and grading or sorting equipment, nets, etc. Quarantines are issued to prevent the spread of specific diseases.

Quarantine facility – a culture system that is enclosed in a building and is separated from other aquatic organism culture facilities where organisms can be isolated and maintained while preventing their introduction and/or associated pathogen introduction into the environment.

Risk – the likelihood and magnitude of the outcome of the unwanted event; a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard exposure.

Risk analysis – the process that includes risk assessment, risk management, and risk communication.

Risk assessment – a scientifically based process for which answers to three questions are sought: (1) what can go wrong (hazard identification); (2) how likely is the hazard to occur; and (3) what is the severity of the effect if it does.

Risk-benefit analysis – a comparison of risks to the benefits inherent in the act being considered. A risk-benefit analysis is broader than a cost-benefit analysis.

Risk communication – the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, customers, and other interested parties.

Risk management – the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

Risk mitigation – the alternatives developed from the risk assessment to reduce the effects of the hazard being evaluated.

Secretary – the Secretary of Agriculture.

Shellfish – any mollusk, crustacean or chelicerata including clams, quahogs, mussels, oysters, whelks, scallops, lobsters, crabs, shrimp, horseshoe crabs, and sea urchins.

Therapeutic agent – any chemical or physical agent, or combination thereof, to which the cultured organisms can be exposed to control, prevent or eliminate an actual or potential disease condition or etiological agent, and which does not adversely effect the viability of the treated organisms above a certain acceptable level for a particular population.

Toxic pollutant – any pollutant identified pursuant to the Federal Act, or any pollutant or combination of pollutants, including disease causing agents, which after discharge and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly or indirectly by ingestion through food chains, will, on the basis of information available to the commissioner, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions, including malfunctions in reproduction, or physical deformation, in such organisms or their offspring.

Transgenic organisms – organisms which are genetically altered by recombinant DNA technology.

Virulence – capacity of a pathogen to effectively invade and establish replicative residence in and overcome the defenses of the host, thus creating a disease state; usually defined in terms of the severity of that state in a typical member of a susceptible population.

Waters of the State – means all fresh and salt waters of the state. Waters contained in ponds, lakes, and aquaculture facilities created by, or under the exclusive control of any individual, shall be considered private waters.

Appendix A Finfish: Viral Pathogens

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis	Treatment / Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Channel Catfish Virus (CCV)	Yellow	Ictaluridae, primarily channel catfish (*Ictalurus punctatus*)	AL, AR, CA, CO, GA, IA, ID, KS, KY, MN, MS. NE, OK, TX, WV and Honduras --- Not known to be present in New Jersey	Presumptive diagnosis – cell culture assay using procedures from AFS-FHS Blue Book 4th edition Confirmatory diagnosis – serum neutralization using procedures from AFS-FHS Blue Book 4th edition Subclinical infections – no suitable procedures have been reported.	Avoidance Use of resistant strains or hybrids No known or approved chemotherapy	CCVD is only know from hatchery-reared catfish and is not considered a threat to wild stocks. However, since it is not know from New Jersey, channel catfish imported for release into the fresh waters of the state must be obtained from hatcheries which have documented a long-term health history free of CCV. To afford maximum protection to the Hackettstown Hatchery channel catfish brood stock, permits to stock catfish into waters where CCVD might pose a threat to that stock will not be allowed. [Similar protection would be afforded to the brood stock of any licensed hatchery which can demonstrate a history free of CCV].	The lack of procedures for detection of subclinical infections eliminates the possible use of inspection and certification of CCV-free stocks. Any catfish obtained for use in aquaculture should be obtained from a source that can demonstrate a long-term health history without CCV. A regional fish health specialist from the area of a potential source stock should be consulted.
Erythrocytic Inclusion Body Syndrome (EIBS)	Yellow	Salmonidae	CA, ID, OR, WA – similar virus in fish from Norway, Ireland and Japan --- Not known to be present in New Jersey	Presumptive diagnosis – light microscopic observation of characteristic cytoplasmic inclusions in blood smears Confirmatory diagnosis – EIBS virus has not yet been isolated in cell culture Subclinical infections – typical inclusions are often seen in fish that do not show overt anemia; however, inclusions are at times difficult to find in fish with severe anemia.	Avoidance	Incomplete characterization of the responsible virus and lack of detection procedures and confirmatory diagnosis eliminates the possible use of inspection and certification of EIBS-free stocks. Natural infections of EIBS have only been reported from species of *Oncorhynchus* (Pacific salmon) and *Salmo salar* (Atlantic salmon) which are not indigenous to New Jersey. Release of those species is not currently allowed.	Incomplete characterization of the responsible virus and lack of detection procedures and confirmatory diagnosis eliminates the possible use of inspection and certification of EIBS-free stocks. Any salmon obtained for use in aquaculture should be obtained from a source that can demonstrate a long-term health history without EIBS. A regional fish health specialist from the area of a potential source stock should be consulted.
Salmonid Herpesviral Diseases [Salmonid herpesvirus 1 also known as Herpesvirus salmonis and Salmonid herpesvirus 2 also known as *Oncorhynchus masou* virus (OMV)]	Red	Salmonidae	WA and CA (Type 1) Japan (Type 2) --- Not known to be present in New Jersey	Presumptive diagnosis – cell culture assay using procedures from AFS-FHS Blue Book 4th edition Confirmatory diagnosis – serum neutralization using procedures from AFS-FHS Blue Book 4th edition Subclinical infections – no suitable procedures have been reported.	Avoidance Iodine disinfection of eggs No approved chemotherapy	Salmonids imported for release in New Jersey fresh waters from within the area where Salmonid herpesvirus is enzootic must be obtained as eggs from facilities which have been annually inspected and found free of the virus for the last three years; eggs must be disinfected with an iodophor compound; no fish which have developed past the egg stage can be directly released into waters of the state. Fish obtained from facilities outside of the enzootic area of Salmonid herpesvirus, but which have received fish from within the enzootic area of Salmonid herpesvirus, must provide documentation that any fish or eggs obtained from that area were inspected and found free of Salmonid herpesvirus.	Stocks obtained from within the enzootic area should be obtained from certified Specific Pathogen-Free (SPF) stocks as eggs only, incubated in virus-free water, and subjected to disinfection upon arrival at the receiving hatchery, Any introduction of salmonids from west of the continental divide in North America or from outside of the continent must be reported to the North Atlantic Salmon Commission (NASCO) and their guidelines must be followed.

Finfish : Viral Pathogens (continued)

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis	Treatment / Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Infectious Hematopoietic Necrosis Virus (IHNV)	Red	Salmonidae	Enzootic on areas of the west coast of North America including AK, WA, ID, OR and CA in the United States and British Columbia, Canada; and the islands of Hokkaido and Honshu of Japan --- Not known to be present in New Jersey	Presumptive diagnosis – cell culture assay using procedures from AFS-FHS Blue Book 4th edition Confirmatory diagnosis – serum neutralization using procedures from AFS-FHS Blue Book 4th edition Subclinical infections – virus can be detected in yearling and adult salmonids exhibiting no clinical signs.	Avoidance Iodine disinfection of eggs Destruction of infected lots No approved chemotherapy	Salmonids imported for release in New Jersey fresh waters from within the area where IHNV is enzootic must be obtained as eggs from facilities which have been annually inspected and found free of IHNV for the last three years; eggs must be disinfected with an iodophor compound; no fish which have developed past the egg stage can be directly released into waters of the state. Fish obtained from facilities outside of the enzootic area of IHNV, but which have received fish from within the enzootic area of IHNV, must provide documentation that any fish or eggs obtained from that area were inspected and found free of IHNV.	Stocks obtained from within the enzootic area should be obtained from certified Specific Pathogen-Free (SPF) stocks as eggs only, incubated in virus-free water, and subjected to disinfection upon arrival at the receiving hatchery, Any introduction of salmonids from west of the continental divide in North America or from outside of the continent must be reported to the North Atlantic Salmon Commission (NASCO) and their guidelines must be followed.
Infectious Pancreatic Necrosis (IPNV)	Yellow	IPN is a disease of salmonid fish; however, IPNV and IPN-like viruses (birnaviruses) have been reported in various nonsalmonid fish and from invertebrates	North America, Europe, Asia, Africa, New Zealand, and South America --- Enzootic in New Jersey prior to 1982, not detected since that time	Presumptive diagnosis – cell culture assay using procedures from AFS-FHS Blue Book 4th edition Confirmatory diagnosis – serum neutralization using procedures from AFS-FHS Blue Book 4th edition Subclinical infections – virus can be detected in yearling and adult salmonids exhibiting no clinical signs.	Avoidance Protected water supply where carrier fish can be excluded No approved chemotherapy	To afford maximum protection to the Pequest Hatchery trout brood stocks and to wild trout populations, permits to stock trout into waters where infected or carrier fish might pose a threat to that stock will not be allowed unless those fish are obtained from certified IPN-free facilities. [Similar protection would be afforded to the brood stock of any licensed hatchery which is certified IPN-free].	Trout brought into any hatchery should be obtained from a certified IPN-free stock. Surface disinfection of eggs is not completely effective in preventing transmission. Birnaviruses which show serological relatedness to IPNV have been reported to cause diseases in some farmed marine species. Any fish used in a marine culture facility should likewise be obtained from a stock which has been tested and found free of any IPN-like birnavirus.
Viral Hemorrhagic Septicemia (VHS)	Red	Causes disease in rainbow trout, brown trout, grayling, whitefish, northern pike, turbot and pacific herring --- Isolated from various wild marine fish species	Freshwater isolates confined to Western Europe --- Isolated from free-living marine species in the North Pacific Ocean, North Atlantic Ocean, North Sea and Baltic Sea --- Not known to be present in New Jersey	Presumptive diagnosis – cell culture assay using procedures from AFS-FHS Blue Book 4th edition Confirmatory diagnosis – serum neutralization using procedures from AFS-FHS Blue Book 4th edition Subclinical infections – virus can be detected in yearling and adult salmonids exhibiting no clinical signs.	Avoidance Iodine disinfection of eggs Destruction of infected lots No approved chemotherapy	Salmonids imported for release in New Jersey fresh waters from within the area where VHS is enzootic must be obtained as eggs from facilities which have been annually inspected and found free of VHS for the last three years; eggs must be disinfected with an iodophor compound.	Stocks obtained from within the enzootic area in Western Europe should be obtained from certified Specific Pathogen-Free (SPF) stocks as eggs only, incubated in virus-free water, and subjected to disinfection upon arrival at the receiving hatchery, Any introduction of salmonids from west of the continental divide in North America or from outside of the continent must be reported to the North Atlantic Salmon Commission (NASCO) and their guidelines must be followed. Since the virus is being reported from an ever-increasing number of marine species, any marine fish used in an aquaculture operation should be from a stock which has been tested and found free of VHS virus.

Finfish : Viral Pathogens (continued)

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis	Treatment/ Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Infectious Salmon Anemia (ISA)	Red	Causes disease in Atlantic Salmon Virus may survive and replicate in brown trout, rainbow trout and Atlantic herring which could act as carriers	Norway, United Kingdom, east coast of Canada , Maine ---------- Not known to be present in New Jersey	Presumptive diagnosis – cell culture assay using procedures from AFS-FHS Blue Book 4th edition Confirmatory diagnosis – RT-PCR to detect ISAV in kidney tissues or to confirm that CPE in cell culture is due to ISAV from AFS-FHS Blue Book 4th edition Subclinical infections – virus can be detected in yearling and adult salmonids exhibiting no clinical signs.	Avoidance No approved chemotherapy	Salmonids imported for release in New Jersey fresh waters from within the area where ISA is enzootic must be obtained as eggs from facilities which have been annually inspected and found free of ISA for the last three years.	Stocks obtained from within the enzootic area should be obtained from certified Specific Pathogen Free (SPF) stocks. The infection is mainly observed in fish held in seawater or in fish exposed to seawater. The reservoirs of infection are not known, but effluent from infected Atlantic salmon farms and slaughterhouses has been implicated in the spread. Other marine fish may be the natural reservoirs of infection. Precautions should be taken in siting both aquaculture and fish processing operations.
Spring Viremia of Carp (SVC)	Red	Common carp and other cyprinid fish species	Europe, possibly Asia and other areas where carp are traditionally reared ---------- Not known to be present in New Jersey	Presumptive diagnosis -- cell culture using FHM, EPC, or BF-2 cell lines. Confirmatory diagnosis – serum neutralization or molecular methods described in the literature Subclinical infections - no suitable procedures have been reported.	Avoidance No approved chemotherapy	The release of carp into the fresh waters of New Jersey is prohibited under current statutes. An exception is made for certified triploid grass carp. Release into or holding of any potential or suspected SVC-carriers of SVC will not be allowed because of possible adverse impacts on native cyprinids.	The lack of procedures for detection of subclinical infections eliminates the possible development and use of SVC-free stocks. Any carp obtained for use in aquaculture should be obtained from a source that can demonstrate a long-term health history without SVC. A regional fish health specialist from the area of a potential source stock should be consulted. Aquaculture operations which raise or breed carp should perform annual virologic examinations on liver/spleen samples of fish from production lots and, using non-lethal methods, on ovarian fluids of brood fish.
Pike Fry Rhabdovirus (PFR)	Red	Disease has only been reported in Northern pike	Europe ---------- Not known to be present in New Jersey	Presumptive diagnosis -- cell culture using FHM or other susceptible cell lines. Confirmatory diagnosis – serum neutralization Subclinical infections - no suitable procedures have been reported.	Avoidance	Since this disease has not been reported in North America, and procedures for detection of carriers and the designation of PFR-free stocks is not possible, introduction of northern pike from within the enzootic area would not be permitted.	Since this disease has not been reported in North America, and procedures for detection of carriers and the designation of PFR-free stocks is not possible, northern pike should not be obtained from within the enzootic area.

Finfish : Viral Pathogens (continued)

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis	Treatment/ Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Esocid Lymphosarcoma	Green	Northern Pike Muskellunge	Canada, United States, Europe --- Not known to be present in new Jersey	Presumptive diagnosis – finding of cutaneous lesions that are grossly and histologically consistent with those described for the disease Confirmatory diagnosis – the virus has not been isolated in cell culture; the presence of C-type particles or experimental transmission of the disease would be the best evidence.	Control in natural waters is unrealistic Known only from adult fish Adult esocids should not be stocked; stocking should be done with eggs, fry, and fingerlings that have been reared in facilities to which adults do not have access	No restriction on movement of fish.	Not considered a problem in captive populations. Eggs, fry and fingerlings of esocid species should be reared in facilities to which adults do not have access. Suspected cases should be reported.
Lymphocystis	Green	Many freshwater and marine species, but only among the more highly evolved fishes	Probably worldwide --- Has been observed on both freshwater and marine species of fish in New Jersey	Presumptive diagnosis – observation of individual or clustered hypertrophied cells on the skin or fins of fishes known to be susceptible Confirmatory diagnosis – histologic sections of infected tissue.	Lymphocystis seldom causes host mortality, lesions are unsightly and affect marketability Avoidance No approved chemotherapy	No restriction on movement of fish. Because of the ubiquitous nature and low virulence, no control measures are practical or necessary.	Aquaculturists should avoid the use of fish with visible lesions.
Viruses of fish species exotic to New Jersey --- Viruses of marine fish species	Red	The diseases and pathogens discussed in the preceding sections were those which have been reported from fish species which are indigenous to the fresh waters of New Jersey. Many viruses, some highly pathogenic, have been reported from fishes which are not indigenous to New Jersey, and their pathogenicity to indigenous species remains untested. The risks associated with viruses are great because they can cause explosive, uncontrollable mortalities, they are untreatable, and there are few approved vaccines for their prevention. Before any non-indigenous species is released or cultured in the fresh waters of the state, comprehensive virological testing should be performed and potential for infecting indigenous species should be assessed. Aquaculture operations which raise or breed exotic species should perform periodic (no less frequent than annual) virologic examinations on liver/spleen samples of fish from production lots and, using non-lethal methods, on ovarian fluids of brood fish. Aquaculture of marine fish species has not been widely practiced in New Jersey, and viral diseases among New Jersey's marine fish species are largely unknown. Because New Jersey's marine fish stocks have not been exposed to viral pathogens associated with aquaculture and because of the great value of the marine fish resource, extreme caution should be exercised. Before any fish species is reared or aquacultured products processed in coastal waters of New Jersey, complete virological testing should be performed and potential for infecting New Jersey's resident and transitory marine fish species should be assessed. Aquaculture operations which raise or breed marine fish species (whether exotic or indigenous) should perform periodic (no less frequent than annual) virologic examinations on liver/spleen samples of fish from production lots and, using non-lethal methods, on ovarian fluids of brood fish.					

Finfish : Bacterial Pathogens

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis	Treatment / Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Bacterial Gill Disease (*Flavobacterium branchiophilum*)	Green	Common in intensively cultured salmonids and in other species in fresh water	Worldwide	Microscopic examination of gill tissue for the presence of long, thin bacteria on the epithelium.	Improve environmental conditions, correct overcrowding No approved chemotherapy Chloramine-T and Diquat have been used	No restrictions on movement of fish. The disease is caused by ubiquitous organisms which cause disease in fish under stress associated with intensive culture.	Provide optimal environmental conditions. Avoid overcrowding, dusty feeds, and excessive silt in water supply. Reduce rearing density or increase flow to avoid reappearance of the disease.
Columnaris (*Flavobacterium columnare*)	Green	All freshwater fishes are considered susceptible	Worldwide	Presumptive diagnosis – microscopic examination of wet mounts of scrapings from lesions and detection of long slender bacteria that form characteristic haystacks or columns – isolation of bacteria that form dry, rhizoid, yellow colonies on cytophaga agar Confirmatory diagnosis – agglutination with specific antiserum or by biochemical testing.	Improve environmental conditions, correct overcrowding No approved chemotherapy Chloramine-T and Terramycin have been used	No restriction on movement of fish. Control in the wild is not practical since the disease is caused by a common water-borne organism.	Provide optimal environmental conditions. Maintain good water quality, optimal temperatures (particularly for salmonids), reduce handling during warm weather, and avoid overcrowding.
Bacterial Coldwater Disease (*Flavobacterium psychrophilum*)	Green	Salmonids	United States, Canada, France, Denmark	Presumptive diagnosis – microscopic examination of wet mounts of scrapings from lesions and detection of long thin gram-negative bacteria – isolation of bacteria that form moist, yellow, raised colonies on cytophaga agar Confirmatory diagnosis – agglutination with specific antiserum or by FAT.	No approved chemotherapy Terramycin has been used	No restrictions on movement of fish . The disease is caused by common water-borne organism which causes disease in fish under stress associated with intensive culture.	Provide optimal environmental conditions. Observe strict sanitary procedures.
Furunculosis, Goldfish Ulcer Disease, Trout Ulcer Disease, Carp Erythrodermatitis (*Aeromonas salmonicida*)	Yellow	Many freshwater and marine species are susceptible	North America, South America, Europe, Asia, and Africa --------- Enzootic in New Jersey although some facilities are Specific-Pathogen-Free	Presumptive diagnosis – isolation of bacteria from diseased fish . Confirmatory diagnosis – agglutination with diagnostic antiserum, FAT or biochemical characterization.	Romet or Terramycin medicated feeds	To afford maximum protection to the Pequest Hatchery trout brood stocks and to wild trout populations, permits to stock trout into waters where infected or carrier fish might pose a threat to that stock will not be allowed unless those fish are obtained from certified *Aeromonas salmonicida*-free facilities. [Similar protection would be afforded to the brood stock of any licensed hatchery which is certified *Aeromonas salmonicida* -free].	Salmonids for aquaculture operations should be obtained from certified stocks. Trout hatcheries should observe strict sanitary procedures, optimal temperatures, adequate dissolved oxygen, efficient waste removal, avoid overcrowding, maintain a water supply free of potential carriers. Any other species of fish for use in aquaculture should be obtained from a source that can demonstrate a long-term health history without *Aeromonas salmonicida.*

Finfish : Bacterial Pathogens (continued)

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis	Treatment/ Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Edwardsiella tarda Septicemia	Green	Various fish species The bacterium also may cause disease in mammals including humans	The bacteria are widespread in the environment Fish disease has been reported in the United States and Southeast Asia	Presumptive diagnosis – isolation of bacteria from diseased fish . Confirmatory diagnosis – agglutination with diagnostic antiserum, FAT or biochemical characterization.	No approved chemotherapy Antibiotics have been used	No restriction on movement of fish. However, the release of fish known to be infected with *Edwardsiella tarda* would not be allowed since it is capable of infecting humans. *Edwardsiella tarda* is not an obligate fish pathogen and is common in the environment, causing disease only when fish are subjected to environmental stress.	Provide optimal environmental conditions. Maintain good water quality and avoid overcrowding.
Enteric Septicemia of catfish (*Edwardsiella ictaluri*)	Green	Channel & white catfish, brown , yellow & black bullhead --- Infections have been reported in some other fish species	United States Thailand ---------- Not known to be present in New Jersey	Presumptive diagnosis – isolation of bacteria from diseased fish . Confirmatory diagnosis – agglutination with diagnostic antiserum or by FAT.	No approved chemotherapy Antibiotics have been used	No restriction on movement of fish. *Edwardsiella ictaluri* is primarily a disease of hatchery-raised fish, causing disease under stress associated with intensive culture.	Provide optimal environmental conditions. Maintain good water quality and avoid overcrowding.
Enteric Redmouth (*Yersinia ruckeri*)	Yellow	Salmonids ----- Infections have been reported in some other fish species	North America, Europe ---------- Not reported from New Jersey	Presumptive diagnosis – isolation of bacteria from diseased fish . Confirmatory diagnosis – biochemical characterization.	Romet or Terramycin medicated feeds	To afford maximum protection to the Pequest Hatchery trout brood stocks and to wild trout populations, permits to stock trout into waters where infected or carrier fish might pose a threat to that stock will not be allowed unless those fish are obtained from certified *Yersinia ruckeri*-free facilities. [Similar protection would be afforded to the brood stock of any licensed hatchery which is certified *Yersinia ruckeri*-free].	Salmonids for aquaculture operations should be obtained from certified stocks. Trout hatcheries should observe strict sanitary procedures, maintain a water supply free of potential carriers.
Vibriosis (*Vibrio* spp.)	Green	All fish species are probably susceptible	Worldwide in the marine environment	Presumptive diagnosis – isolation of bacteria from diseased fish . Confirmatory diagnosis – sensitivity to a vibriostatic agent.	No approved chemotherapy Antibiotics have been used	No restriction on movement of fish. *Vibrio* spp. are common in the environment, causing disease only when fish are subjected to environmental stress.	Provide optimal environmental conditions. Maintain good water quality and avoid overcrowding.
Motile Aeromonas Septicemia (*Aeromonas hydrophila* and related organisms)	Green	All freshwater fishes, as well as frogs, turtles and snakes are considered susceptible	Worldwide	Presumptive diagnosis – isolation of bacteria from diseased fish . Confirmatory diagnosis – biochemical characterization.	Terramycin medicated feeds	No restriction on movement of fish. *Aeromonas* spp. are common in the environment, causing disease only when fish are subjected to environmental stress.	Provide optimal environmental conditions. Maintain good water quality and avoid overcrowding. Control outbreaks with chemotherapeutics.

Finfish: Bacterial Pathogens (continued)

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis	Treatment/ Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Bacterial Kidney Disease (*Renibacterium salmoninarum*)	Yellow	Salmonids	North America, South America, Europe, Asia --- Not reported from New Jersey since 1979	Presumptive diagnosis – Presence of small, gram-positive non-acid-fast diplobacilli that occur both intracellularly and extracellularly in smears or histological sections Confirmatory diagnosis – FAT, ELISA, or culture on specialized media.	Avoidance No approved chemotherapy Drugs have proven effective only in delaying mortality and not in eliminating infections	To afford maximum protection to the Pequest Hatchery trout brood stocks and to wild trout populations, permits to stock trout into waters where infected or carrier fish might pose a threat to those stocks will not be allowed unless those fish are obtained from certified *Renibacterium salmoninarum*-free facilities. [Similar protection would be afforded to the brood stock of any licensed hatchery which is certified *Renibacterium salmoninarum* -free].	Salmonids for aquaculture operations should be obtained from certified *Renibacterium salmoninarum*-free stocks.
Piscirickettsiosis (*Piscirikketsia salmonis*)	Yellow	Salmonids	Chile, Ireland, Norway, and both west and east coasts of Canada --- Not known to be present in New Jersey	Presumptive diagnosis – cell culture assay using procedures from AFS-FHS Blue Book Confirmatory diagnosis – IFAT Subclinical infections – no suitable procedures have been reported.	Avoidance Egg disinfection and antibacterial treatment may be of some value	This pathogen is not specifically addressed by current policy; however, anadromous salmonids or salmonids from the geographic areas from which *Piscirikketsia salmonis* have been reported could not be imported without health history assessment.	This disease has been primarily reported from marine fish farms. Stock selection, water supply and potential carriers in the marine environment should be considered before siting any marine culture operation involving salmonids. Transfer of fish from the marine environment to freshwater facilities should be avoided.
Streptococcal Infections (*Streptococcus iniae*)	Yellow	Warmwater fish -- both freshwater and marine --- Considered a zoonotic agent capable of infecting humans	Worldwide	Presumptive diagnosis – isolation of bacteria from diseased fish . Confirmatory diagnosis – biochemical characterization.	No approved chemotherapy Antibiotics have been used	No restriction on movement of fish. However, release of known infected fish would not be allowed because *Streptococcus iniae* is capable of infecting humans.	Provide optimal environmental conditions. Maintain good water quality and avoid overcrowding.
Mycobactreriosis (*Mycobacterium* spp.)	Yellow	Reported from various freshwater and marine species	Worldwide	Presumptive diagnosis – presence of acid-fast bacteria in stained smears from fish showing clinical signs of the disease Confirmatiry diagnosis – isolation and characterization of the bacteria.	No approved chemotherapy	No restriction on movement of fish. However, release of known infected fish would not be allowed because *Mycobacterium* spp. are capable of infecting humans.	Provide optimal environmental conditions. Maintain good water quality and avoid overcrowding. Practice strict sanitation (cleaning and disinfection of equipment and rearing facility).
Other Bacterial Pathogens		Other bacterial species have been reported to cause disease in captive fish populations or from other parts of the world. These include *Lactobacillus, Serratia, Hafnia, Proteus, Pseudomonas, Citrobacter, Nocardia, Acinetobacter, Pasteurella*, and *Plesiomonas*. In many cases these are opportunistic pathogens or secondary invaders. Aquaculturists should be advised to maintain good water quality , sanitation and optimal rearing conditions. Before any non-indigenous species is released or cultured in the fresh waters of the state, comprehensive bacteriological testing should be performed and potential for infecting indigenous species should be assessed. Aquaculture operations which raise or breed exotic species should perform routine fish health examinations and seek veterinary assistance in cases of suspect bacterial infections.					

Finfish : Parasites and Parasitic Diseases

Pathogen/Disease	Classification	Species Affected	Known Geographic Range	Sampling/Diagnosis Treatment/Control	Policy regarding release of fish into the fresh waters of New Jersey	Recommendations for aquaculture systems
Endemic parasites	Green	Various	Parasites which have been found on wild fish in New Jersey	Formalin (Parasite-S) is FDA-approved as a bath treatment for external protozoan parasites on finfish. General methods of parasite control measures are: maintenance of water supplies free of fish, exclusion of fish-eating birds (which may act as hosts of some parasites) from rearing ponds, monitoring of fish health by microscopic examination of fish tissues, and careful selection of stocks for use in fish culture. Elimination of alternative hosts such as snails and bivalve molluscs.	No restriction on fish obtained from known sources which provide health history information if no exotic parasites are present. Transfers of wild fish within the state (e.g. fish salvage operations) should be limited to waters within the same drainage whenever possible.	Disease problems associated with parasites are more common in fish culture than problems with any other category of fish pathogen. Parasites are commonly found on fish reared under extensive or intensive conditions. When present in small numbers, most pose no problem; however, under adverse conditions or when present in large numbers, even normally benign parasites can become pathogenic. Some parasites, while not pathogenic, by their mere presence in or on the fish can affect the quality or desirability of the fish for consumption.
Non-endemic parasites	Yellow/Red	Various	Parasites not known to be present on wild fish in New Jersey		Stocking permits will not be issued for the release of fish which are infected with parasites not known to be present in New Jersey waters, unless it is demonstrated that they will not have an adverse impact on indigenous fish populations.	
	Parasites exist with their hosts (and parasite populations with host populations) in a natural balance where the parasite exists (at least in some stage of its life) at its hosts expense; however, that expense cannot be so great as to cause irreparable harm to the host, since that would also cost the parasite its life. Therefore, under normal conditions, a parasite should not be pathogenic (i.e. cause disease) in its host. The presence of parasites in a normal host-parasite relationship does not usually create a problem for either fish culturists or to fisheries resource managers. When parasite infections result in disease, there is cause for concern. Disease can result when the host-parasite balance is upset (when environmental conditions shift to favor the pathogen), or when the balance is never established (when a parasite and host are brought together for the first time). While the presence of some parasites on fish is unavoidable, it should be the goal of the aquaculturist to maintain conditions that do not favor the parasite or compromise the host's defense mechanisms. The introduction of a parasite into a population of previously unexposed fish can cause disease. Therefore, the introduction of any parasites not already present in New Jersey should be avoided unless it can be demonstrated that there will be no adverse impact on existing fish populations.					

Finfish : Parasites and Parasitic Diseases (continued)

Parasite Group	Associated Diseases	Treatment / Control	Potential Pathogens not Found in New Jersey	Species Found in New Jersey
Protozoa	Ich, Trichodiniasis, Ichthyobodiasis, Amyloodiniosis, velvet, rust disease, Cryptobiosis, Trypanosomosis, amebic gill disease	Avoidance, protection of water supply, maintenance of optimal environmental conditions for fish. External infections can be treated with Formalin.	*Cryptobia*	*Chilodonella cyprini, Chilodonella hexasticha, Hexamita salmonis, Ichthyobodo pyriformis, Ichthyobodo necator, Ichthyophthirius multifilis, Scyphidia micropteri, Trichodina renicola, Trichodina* spp., *Trichodinella* spp., *Tripartiella* spp., *Trichophrya* spp.
Microsporidia	Heterosporosis	Avoidance	*Heterosporis* sp. of yellow perch and walleye	*Glugea anomala, Glugea pimephales, Glugea stephani, Pleistophora macrozoarcidis, Pleistophora ovariae*
Myxosporidia	Whirling disease, Proliferative kidney disease, Hamburger gill disease	Avoidance	*Myxobolus cerebralis* (whirling disease), *Ceratomyxa shasta,* PKX organism	*Henneguya* spp., *Henneguya episclera, Henneguya exilis, Myxidium giardi, Myxidium lieberkuhni, Myxobolus* spp., *Myxobolus dechtiari, Myxidium* spp.
Monogenea	Gill flukes	Avoidance, exclusion of fish from water supply. External infections can be treated with Formalin.	*Gyrodactylus salaris*	*Actinocleidus fergusoni, Actinocleidus georgiensis, Actinocleidus oculatus, Actinocleidus recurvatus, Actinocleidus sigmoideus, Clavunculus bursatus, Cleidodiscoides sulcata, Cleidodiscus brachus, Cleidodiscus robustus, Cleidodiscus vancleavi, Dactylogyrus* spp., *Dactylogyrus attenuatus, Dactylogyrus banghami, Dactylogyrus dubius, Dactylogyrus extensus, Dactylogyrus minutus, Gyrodactylus* spp., *Haplocleidus adsimulatus, Haplocleidus anchorea, Haplocleidus dispar, Haplocleidus furcatus, Icelanonchohaptor fryvei, Ligictaluridus pricei, Ligictaluridus mirabilis, Octomacrum lanceatum, Octomacrum microconfibula, Onchocleidus attenuatus, Onchocleidus carolinensis, Onchocleidus ferox, Onchocleidus pomotis, Onchocleidus principalis, Onchocleidus tuberculatus, Ornithodiplostomum ptychocheilus, Pterocleidus acer, Pterocleidus nactus, Salsuginus* spp., *Syncleithrium fusiformis, Tetracleidus capax, Tetracleidus stentor, Urocleidus adspectus*
Trematodes		Avoidance, exclusion of birds from rearing facility , protection and exclusion of fish from water supply, exclusion or elimination of first alternative hosts.	*Sanguinicola*	*Allocreadium ictaluri, Allocreadium lobatum, Alloglossidium geminum, Ascocotyle* sp., *Azygia angusticauda, Azygia longa, Bucephalus pusillus, Bunodera sacculata, Clinostomum marginatum, Crepidostomum cooperi, Crepidostomum cornutum, Crepidostomum farionis, Crepidostomum isostomum, Diplostomum spathaceum, Lepocreadium trullaforme, Lissorchis attenuatus, Lissorchis mutabile, Lissorchis* sp., *Macroderoides flavus, Phyllodistomum* spp., *Pisciamphistoma stunkardi, Plagioporus serotinus, Plagioporus sinitsini, Posthodiplostomum minimum, Stephanostomum tenue, Tetracotyle* sp., *Uvulifer ambloplitis*
Cestodes	Asian tapeworm	Avoidance, exclusion of fish from water supply, exclusion of definitive hosts.	*Diphyllobothrium*	*Biacetabulum meridianum, Bothriocephalus acheilognathi, Bothriocephalus claviceps, Bothriocephalus formosus, Corallobothrium fimbriatum, Dilepis* sp., *Glaridacris catostomi, Glaridacris laruei, Hunterella nodulosa, Isoglaridacris agminis, Isoglaridacris bulbocirrus, Megathylacoides giganteum, Monobothrium hunteri, Penarchigetes fessus, Pliovitellaria wisconsinensis, Proteocephalus ambloplitis, Proteocephalus macrocephalus, Proteocephalus pinguis, Rowardleus pennensis.*
Nematodes		Avoidance, exclusion of fish from water supply.	*Truttaedacnitis, Philometra Philonema*	*Anguillicola crassus, Camallanus oxycephalus, Cystidicoloides ephemeridarum, Dichylene cotylophora, Eustrongylides ignotus, Goezia* sp., *Hedruris tiara, Paraquimperia aditum, Rhabdochona canadensis, Rhabdochona ovifilamenta, Spinbitectus carolini, Spinitectus gracilis, Spiroxys* sp.
Acanthocephalans		Avoidance, exclusion of fish from water supply.		*Acanthocephalus dirus, Fessisentis friedi, Leptorhynchoides thecatus, Neoechinorhynchus cylindratus, Neoechinorhynchus prolixoides, Neoechinorhynchus saginatus, Neoechinorhynchus tenellus, Paratenuisentis ambiguus, Pomphorhynchus bulbocolli*
Crustacea	Fish lice	Avoidance, exclusion of fish from water supply.	*Salmincola*	*Argulus* sp., *Ergasilus centrarchidarum, Ergasilus versicolor, Ergasilus caeruleus, Lernaea elegans*

Appendix A Eastern oyster, *Crassostrea virginica*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/ Transport	Comments/NJ History
Juvenile Oyster Disease (JOD)	YELLOW Kills juvenile oysters <25mm in high-density cultures.	Summer Principal symptom is a ring of conchiolin on the inner shell. Similar symptom seen occasionally in wild oysters, but probably has a different cause and should not be considered a problem.	Use selected strains, reduce culture density and increased water flow in culture containers.	There is no evidence that the disease has a hatchery origin. Nursery seed from regions that have experienced JOD should be inspected.	Causative agent unknown, but transmissible; probably has bacterial etiology, but may also involve other factors. Not been reported in NJ, but caused mortalities from NY to ME during the 1990s. Problem subsided in most regions in late 1990s.
Buchephalus sp. (trematode)	GREEN Mostly rare, but prevalence may be elevated in some areas.	Can be found at any season. Tissue section histology or fresh smears.	N/A	Not needed	Not lethal or particularly deleterious, although it typically castrates the host
Haplosporidium nelsoni (MSX) (protist)	GREEN Highly lethal; present throughout NJ waters.	October-December Tissue section histology or PCR diagnosis. Diagnosis using hemolymph detects systemic, but not localized, infections.	Low salinity (≤10 ppt, ≥2 wks, ≥20^{o} C) can eliminate infections. Selected stocks are highly resistant.	Should be based on known history of the parasite in the area and how the hatchery/nursery treats incoming water. Avoid transporting juvenile oysters or stocks that have associated organisms.	Present in NJ since at least 1956. Delaware Bay oysters are now very resistant. Method of transmission unknown, but does not appear to be direct for adult oysters. Juveniles carry spore stage, which is probably a transmission stage.
Haplosporidium costale (SSO) (protist)	GREEN Highly lethal; present in high salinity NJ waters.	May-July in high salinity coastal areas. Tissue section histology. DNA primers available, but not tested for use in diagnosis.	Low salinity will probably eliminate infections, but no experimental evidence available.	Should be based on known history of the parasite in the area and how the hatchery/nursery treats incoming water. Transportation of known infected stocks not recommended.	Known in NJ since early 1960s, but rare and not associated with mortality. Method of transmission unknown, but may be direct. Spores, the presumed transmission stage, are present in adults.
Hemic neoplasia	GREEN Very rare	Can be found at any season. Tissue section histology or hemolymph smears.	N/A	Not needed	Etiology unknown, but reported to have genetic or environmental links. Probably lethal, but not contagious and never associated with commercially significant mortality.

Appendix A Eastern oyster, *Crassostrea virginica*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/Transport	Comments/NJ History
Hexamita sp. (protist)	GREEN Ubiquitous at low prevalence.	Most prominent during cold weather. Tissue section histology or fresh smears.	N/A	Not needed	Considered an opportunist that proliferates in oysters that are inactive during cold weather.
Muscle Pustule	GREEN Ubiquitous at low prevalence.	Can be found at any season by visual inspection of muscle scar on inner valve.	N/A	Not needed	Appears as a pus-filled blister indicative of a response to irritation at the muscle attachment by any biotic (boring organism) or abiotic (sand or shell) object.
Perkinsus marinus (DERMO) (protist)	GREEN Highly lethal; present throughout NJ waters.	September/October Incubation of tissues in Ray's Fluid Thioglycollate Medium (RFTM) is the standard method.	Low salinity will lessen effects of infection, but not eliminate the parasite.	Should be based on known history of the parasite in the area and how the hatchery/nursery treats incoming water. Do not transport bivalves from enzootic areas into *P. marinus* "free" regions.	Present in NJ since early 1950s, when it was probably introduced with commercial importation of southern oysters. Was not associated with mortality, and became essentially undetectable from early 1960s to 1990, when an epizootic outbreak, associated with a winter warming trend, began. Currently the most serious oyster pathogen in NJ. Transmitted directly and is extremely contagious.
Pinnotheres ostreum (pea crab)	GREEN May be present on the gills of oysters.	Females visible in shucked oysters because they are bright orange. Males much smaller and not colored.	N/A	Not needed	Abundance is cyclic. Not lethal or particularly deleterious; considered a food delicacy by some.
Polydora websteri Polychaete worm causing blisters on inner valves.	GREEN Ubiquitous, may be heavy in older oysters.	Can be found at any season in oysters > ~1yr. Inspection of inner shells.	N/A?	Not needed	Infestation may be aggravated if oysters are infected with microparasites. Can be associated with reduced meat quality. Not lethal or particularly deleterious, although detracts from marketability of "half-shell" oysters.

Appendix A Eastern oyster, *Crassostrea virginica*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/ Transport	Comments/NJ History
Rickettsiales-Chlamydiales-like organisms (intracellular bacteria-like)	GREEN Ubiquitous in all marine bivalve species examined.	Can be found at any season. Tissue section histology.	N/A	Not needed	Has been associated with mortality of marine bivalves, but not necessarily as the causative agent – more probably opportunist. Found more frequently in dense associations of bivalves (e.g., nurseries or culture parks).
Other trematodes, cestodes, nematodes, ciliates, and flagellates	GREEN Ubiquitous at low prevalence.	Can be found at any season. Tissue section histology or fresh smears.	N/A	Not needed	Not deleterious See references for species descriptions.

Appendix A Hard clam, *Mercenaria mercenaria*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/ Transport	Comments/NJ History
Diplothyra smithii (boring clam)	GREEN Very rare	Inspection of shells for burrow holes.	N/A	Not needed	Restricted to clams that have not burrowed, so may be an indicator of stressed animals.
Gonadal neoplasia	GREEN Not contagious or lethal.	Tissue section histology.	Avoid *M. mercenaria* x *M. campechiensis* hybrids.	N/A	Reported in southeastern US and highly linked to *M. mercenaria* x *M. campechiensis* hybrids.
Mallacobdella grossa.	GREEN Present at low prevalence.	Examination of mantle cavity using a dissection microscope. Larger worms may be visible by eye.	N/A	Not needed	Found most often in larger clams (<4%). Not deleterious.
Polydora websteri Polychaete worm causing blisters on inner valves	GREEN Ubiquitous but rare.	Can be found at any season by inspection of inner shells.	N/A	Not needed	Restricted to clams that have not burrowed, so may be an indicator of stressed animals.
Quahog Parasite X (QPX) (protist)	GREEN Currently found in clam-growing regions in NJ; associated with high mortality of clams from southern, but not New Jersey broodstock.	Tissue section histology of clams ≥1yr old; most prevalent in spring and fall. Symptoms of heavy infections often visible by eye as swellings or nodules on the mantle edge.	None available, although use of seed from local broodstock is advised. Reduce density and grow clams in appropriate locations.	There is no evidence that QPX is present in seed clam tissues where it could be detected by histology. All evidence indicates clams become infected in growout sites.	Group to which QPX belongs is ubiquitous in marine/estuarine waters. First found in NJ in 1976 associated with overwinter mortality of wild clams in Barnegat Bay. Most likely an opportunist in otherwise compromised clams.
Rickettsiales-Chlamydiales-like organisms (intracellular bacteria-like)	GREEN Ubiquitous in all marine bivalve species examined.	Can be found at any season using tissue section histology.	N/A	Not needed	Has been associated with mortality of marine bivalves, but not necessarily as the causative agent – more probably opportunist. Found more frequently in dense associations of bivalves (e.g., nurseries or culture parks).
Various ciliates, flagellates, trematodes, cestodes and nematodes	GREEN Ubiquitous but rare.	Can be found at any season using tissue section histology or fresh smears.	N/A	Not needed	Not deleterious.

Appendix A Surf Clam, *Spisula solidissima*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/Transport	Comments/NJ History
Sulcascaris sulcata Larval nematode	GREEN Present (2 to 32%) in wild stocks off midAtlantic.	Tissue-section histology or in fresh or frozen tissues viewed by dissecting microscope. May be visible by eye if worm is infected by the haplosporidian parasite *Urosporidium spisuli.*	N/A	Not needed	No reported deleterious effect although presence of worms colored brown by presence of *U. spisuli* may detract from meat appearance. Marine turtle intermediate host.

Note: There is little information on parasites, symbionts, and diseases of surf clams; however, it is likely that they carry the usual complement of Rickettsiales/Chlamydiales-like organisms, ciliates, flagellates, and worms.

Appendix A Blue mussel, *Mytilus edulis*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/Transport	Comments/NJ History
Disseminated neoplasia	YELLOW Contagious (in west coast *M. trossulus*). Not a reported problem in *M. edulis* on the east coast.	Examination of blood smears or tissue-section histology.	No known treatment	Probably not useful for transfers along the east US coast; restrict/prevent transfers from west US coast.	Prevalence on east coast <4%. Found at higher prevalence in US west coast mussels, but may be a consequence of senescence in these short-lived mussels. Not reported in NJ, but sample size very small.
Haplosporidium spp. (protist)	YELLOW Very rare; effect on population unknown but probably negligible.	Tissue-section histology.	No known treatment	Reported prevalences so low that seed inspection not very useful.	*H. tumefacientis* found in *Mytilus californianus* in CA; another haplosporidian found at low prevalence in *M. edulis* in ME. Not reported in NJ, but sample size very small.
Mytilicola spp. (copepods)	GREEN Low prevalence in the US and not pathogenic.	Present in the stomach and intestine/ can be detected by cutting open the stomach; also can be found in gut lumina in tissue sections.	No known treatment	Not needed	May be present at high prevalence (Europe), but rarely reported to be deleterious.
Pseudoklossia sp. (Kidney coccidia)	GREEN Reported, but rare, on the east coast of US, but not known to be a problem.	Tissue-section histology; present in kidney epithelial cells or around kidney tubules.	No known treatment	Reported prevalences so low that seed inspection not very useful.	Not deleterious; present in all other bivalve groups examined.
Rickettsiales-Chlamydiales-like organisms (intracellular bacteria-like)	GREEN Ubiquitous in all marine bivalve species examined.	Can be found at any season Tissue section histology.	N/A	Not needed	Has been associated with mortality of marine bivalves, but not necessarily as the causative agent – more probably opportunist. Found most frequently in dense associations of bivalves (e.g., nurseries or culture parks).

Appendix A Blue mussel, *Mytilus edulis*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/Transport	Comments/NJ History
Steinhausia (=Chytridiopsis) mytilovum	GREEN Low prevalence with no reported adverse effect on population.	Tissue section histology - intracellular in eggs; may elicit host response in the form of hemocyte infiltration.	No known treatment.	Parasite may be transmitted vertically from broodstock, but need for inspection dubious because of low prevalence and lack of deleterious effect.	Not known to be deleterious at the individual or population level, although individual infected eggs may be compromised.
Various ciliates, flagellates, trematodes, cestodes and nematodes	GREEN Ubiquitous at low prevalence.	Can be found at any season by tissue section histology or fresh smears.	N/A	Not needed	Not deleterious, but encysted trematodes may lead to pearl formation, which diminishes food value.

Appendix A Soft shell clam, *Mya arenaria*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/Transport	Comments/NJ History
Perkinsus chesapeaki	RED Effect on clams uncertain, but probably lethal; status in NJ unknown.	Rays Fluid Thioglycollate Medium incubation of rectal and other tissues, or tissue section histology, during late summer/fall.	No known treatment	Required	Newly described from *M. arenaria* in Chesapeake Bay, where it may be associated with mortality. Incidence appears to have increased recently, in parallel with range extension of *P. marinus* in oysters. No sampling in NJ.
Disseminated neoplasia	YELLOW Probably contagious via transplantation of neoplastic cells from affected to nearby unaffected clams.	Examination of blood smears or tissue section histology; highest prevalences in fall and winter.	Reduce density; harvest early; avoid introduction of affected stocks.	Not very useful as this is a field-acquired disease that seems to increase with age.	Found in northern NJ coastal locations.
Gonadal neoplasia	GREEN Not contagious or lethal, but impairs reproduction.	Tissue section histology.	No known treatment	N/A	Reported in northeastern US. No sampling in NJ.
Rickettsiales-Chlamydiales-like organisms (intracellular bacteria-like)	GREEN Ubiquitous in all marine bivalve species examined.	Can be found at any season using tissue section histology.	N/A	Not needed	Has been associated with mortality of marine bivalves, but not necessarily as the causative agent – more probably opportunist. Found more frequently in dense associations of bivalves (e.g., nurseries or culture parks).
Various ciliates, flagellates, trematodes, cestodes and nematodes	GREEN Ubiquitous but rare.	Can be found at any season using tissue section histology or fresh smears.	N/A	Not needed	Not deleterious

Appendix A Bay Scallop, *Argopecten irradians*

Parasite/Symbiont/ Disease	Risk	Sampling Time/Diagnosis	Treatment/Amelioration	Hatchery Certification/ Health Inspection/ Transport	Comments/NJ History
"Perkinsus" karlssoni	YELLOW effect on scallops and identification of parasite uncertain. No clear association with mortality.	Ray's Fluid Thioglycollate Medium and tissue section histology; proliferates at temperatures > 20C.	No known treatment	Advisable since it is thought that "the parasite" is transmitted during spawning.	No longer considered a "Perkinsus" species; probably misidentified using stages from several organisms; found in eastern Canada and New England; effects difficult to distinguish from normal post-spawning mortality. No NJ scallops examined.
Polydora websteri Polychaete worm causing blisters on inner valves	GREEN Ubiquitous	Can be found at any season by inspection of inner valves.	N/A?	Not needed	May impair ability of scallops to swim.
Pseudoklossia sp. (kidney coccidia)	GREEN Present in bay scallops in New England	Tissue section histology; present in kidney epithelial cells or around kidney tubules; squash preparation of kidney tissues.	No known treatment	Not needed	Associated mortalities in other scallop species seem to be linked to artificial culture conditions and have not been reported in bay scallops; present in all other bivalve groups examined. No NJ scallops examined.
Rickettsiales-Chlamydiales-like organisms (intracellular bacteria-like)	GREEN Ubiquitous in all marine bivalve species examined.	Can be found at any season. Tissue section histology.	N/A	Not needed	Has been associated with mortality of marine bivalves, but not necessarily as the causative agent – more probably opportunist. Found more frequently in dense associations of bivalves (e.g., nurseries or culture parks).
Tumidotheres (=*Pinnotheres*) *maculatus* (pea crab)	GREEN Ubiquitous	Females visible in shucked scallops because they are bright orange. Males much smaller and not colored.	N/A	Not needed	Not lethal or particularly deleterious; considered a food delicacy by some.
Various ciliates, flagellates, trematodes, cestodes and nematodes	GREEN Ubiquitous at low prevalence.	Can be found at any season Tissue section histology or fresh smears.	N/A	Not needed	Not deleterious See references for species descriptions.

Note: Species of *Haplosporidium*, *Marteilia*, and *Perkinsus* have been found in other scallop species. *Marteilia* sp. was associated with mass mortality of calico scallops (*Argopecten gibbus*) in Florida. *Perkinsus qugwadi* causes disease and mortality in the introduced Japanese scallop, *Patinopecten yessonesis*, in British Columbia, Canada.

OIE Appendix

OIE Office of International Epizooties

The *Office International des Epizooties* (OIE) is a global organization focusing on animal health issues in 147 member countries. The Fish Diseases Commission, a Specialist commission of the OIE, makes import and export recommendations for aquatic animals and aquatic animal products, which includes finfish, molluscs, and crustaceans. Member countries are required to adopt protocols outlined in the Aquatic Animal Health Code and Diagnostic Manual for Aquatic Animal Diseases for diagnosing and eradicating diseases listed as reportable or significant. Many foreign countries require testing for pathogens that are reportable by the OIE before export from the United States.

Diseases Reportable to OIE (*www.oie.int/norms/fcode/a_summry.htm*)

I. Finfish

A. Epizootic haematopoietic necrosis (EHN); **Susceptible hosts**: redfin perch (*Perca fluviatilis*), rainbow trout (*Oncorhynchus mykiss*), Macquarie perch (*Macquaria australasica*), mosquito fish (*Gambusa affinis*), silver perch (*Bidyanus bidyanus*) and mountain galaxias (*Galaxias olidus*)

B. Infectious haematopoietic necrosis (IHN); **Susceptible hosts**: rainbow or steelhead trout (*Oncorhynchus mykiss*), several Pacific salmon including sockeye salmon (*O. nerka*), chinook salmon (*O. tshawytscha*), chum salmon (*O. keta*), yamame salmon (*O. masou*), amago salmon (*O. rhodurus*) and coho salmon (*O. kisutch*), and Atlantic salmon (*Salmo salar*)

C. *Oncorhynchus masou* virus disease (OMVD); **Susceptible hosts**: kokanee salmon (*Oncorhynchus nerka*), masou salmon (*O. masou*), chum salmon (*O. keta*), coho salmon (*O. kisutch*) and rainbow trout (*O. mykiss*)

D. Spring viraemia of carp (SVC); **Susceptible hosts**: common carp (*Cyprinus carpio*), grass carp (*Ctenopharyngodon idellus*), silver carp (*Hypophthalmichthys molitrix*), bighead carp (*Aristichthys nobilis*), crucian carp (*Carassius carassius*), goldfish (*Carassius auratus*), tench (*Tinca tinca*) and sheatfish (*Silurus glanis*)

E. Viral haemorrhagic septicaemia (VHS); **Susceptible hosts**: rainbow trout (*Oncorhynchus mykiss*), brown trout (*Salmo trutta*), grayling (*Thymallus thymallus*), white fish (*Coregonus spp.*), pike (*Esox lucius*), turbot (*Scophthalmus maximus*), herring and sprat (*Clupea spp.*), Pacific salmon (*Oncorhynchus spp.*), Atlantic cod (*Gadus morhua*), Pacific cod (*G. macrocephalus*), haddock (*G. aeglefinus*) and rockling (*Onos mustelus*)

II. Molluscs

A. Bonamiosis; *Bonamia ostreae*- **Susceptible hosts**: *Ostrea edulis, O. angasi, O. denselammellosa, O. puelchana, Ostreola conchaphila* (= *O. lurida*) and *Tiostrea chilensis; Bonamia sp.*- **Susceptible hosts**: *Tiostrea chilensis* and *Ostrea angasi*

B. MSX Disease and SSO disease; *Haplosporidium costale* and *H. nelsoni*- Susceptible host: *Crassostrea virginica*

C. Marteiliosis- *Marteilia refringens*; **Susceptible hosts**: *Ostrea edulis, O. angasi* and *Tiostrea chilensis*; *M. sydneyi*- **Susceptible host***: Saccostrea (= Crassostrea) commercialis*

D. Mikrocytosis; *Mikrocytos mackini*- **Susceptible hosts**: *Crassostrea gigas, C. virginica, Ostrea edulis* and *O. conchaphila; M. roughleyi*- **Susceptible host**: *Saccostrea commercialis*

E. Perkinsosis; *Perkinsus marinus*- **Susceptible hosts**: *Crassostrea virginica* and *C. gigas*; *P. olseni*- **Susceptible hosts**: *Haliotis ruber* and *H. laevigata*

III. Crustaceans

A. Taura Syndrome

B. White spot disease

C. Yellowhead disease

OIE Significant Diseases

I. Finfish

A. Channel catfish virus disease (CCV) (herpesvirus of Ictaluridae type 1)

B. Viral encephalopathy and retinopathy

C. Infectious pancreatic necrosis (IPN)

D. Infectious salmon anaemia (ISA)

E. Epizootic ulcerative syndrome

F. Bacterial kidney disease (BKD) (*Renibacterium salmoninarum*)

G. Enteric septicaemia of catfish (ESC) (*Edwardsiella ictaluri*)

H. Piscirickettsiosis (*Piscirickettsia salmoninarum*)

I. Gyrodactylosis (*Gyrodactylus salaris*)

J. Red sea bream iridoviral disease

K. White sturgeon iridoviral disease

II. Molluscs

III. Crustaceans

A. Baculoviral midgut gland necrosis

B. Nuclear polyhedrosis baculoviroses (*Penaeus monodon*-type baculovirus and *Baculovirus penaei*)

C. Infectious hypodermal and haematopoietic necrosis virus

D. Crayfish plague (*Aphanomyces astaci*)

E. Spawner-isolated mortality virus disease

Appendix C

Appendix Therapeutics

A. Drugs Approved for Use in Aquaculture (Poikilothermic Food Species)

Drug	Species	Indication	Dosage regimen	Limitations/Comments
Chorionic Gonadotropin, (Chorulon® by et, Inc.)	Male and female brood finfish	Aid in improving spawning function	50 to 510 IU/lb males 67 to 1816 IU/lb females	Up to three doses. Total dose not to exceed 25,000 IU in fish intended for human consumption
Oxytetracycline monoalkyl trimethyl ammonium (Terramycin® by Pfizer, Inc.)	Pacific salmon	Mark skeletal tissue	250 mg/kg/day for 4 days	--Salmon < 30 g In feed as sole ration -- 7 day withdrawal time Also hydrochloride form
	Salmonids	Control ulcer disease furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease,(*Hemophilus piscium, Aeromonas salmonicida, A. . liquefaciens, Pseudomonas*)	2.5 to 3.75 g/100 lb/day for 10 days	--In mixed ration -- Water temperature not below 48.2° F --21 day withdrawal time
	Catfish	Control bacterial hemorrhagic septicemia and pseudomonas disease (*A. liquefaciens*, *Pseudomonas*)	2.5 to 3.75 g/100 lb/day for 10 days	--In mixed ration -- Water temperature not below 62° F --21 day withdrawal time
	Lobster	Control gaffkemia (*Aerococcus viridans*)	1 g/lb medicated feed for 5 days	--In feed as sole ration --30 day withdrawal time
Sulfadimethoxine ormetoprim (Romet-30®by Roche Vitamins, Inc.)	Salmonids	Control furunculosis (*Aeromonas salmonicida*)	50 mg/kg/days for 5 days	--In feed --42 day withdrawal time
	Catfish	Control enteric septicemia (*Edwardsiella ictaluri*)	50 mg/kg/days for 5 days	--In feed --3 day withdrawal time

Appendix C

Drugs Approved for Use in Aquaculture (Poikilothermic Food Species)

Drug	Species	Indication	Dosage regimen	Limitations/Comments
Tricaine methanesulfonate	Fish (Ictaluridae, Salmonidae, Esocidae, Percidae) Other aquatic poikilotherms	Sedation/anesthesia	15 to 330 mg/L (fish) 1:1,000 to 1:20,000 (other poikilotherms)	--Powder is added to water --Concentration depends upon , desired degree of anesthesia, species, size, water temperature and softness, stage of development; preliminary tests of solution should be made with a few fish --21 day withdrawal time (fish); laboratory or hatchery use only in other poikilotherms --Water temperature over 50° F
Formalin -Formalin-F® by Natchez Animal Supply Co. & Paracide-F® by Argent Laboratories	Select finfish: salmon, trout, catfish, bluegill, largemouth bass	Control protozoa (*Chilodonella, Costia, Epistylis, Ichthyophthirius, Scyphidia, Trichodina* spp.) and monogenetic trematodes (*Cleidodiscus, Dactylogyrus, Gyrodactylus* spp.)	Tanks and raceways: Salmon & trout Above 50°F: up to 170 µl/L; up to 1 hr Below 50°F: up to 250 µl/L; up to 1 hr Catfish, bluegill, largemouth bass up to 250 µl/L; up to 1 hr Earthern ponds: 15 to 25 µl/L; indefinitely	--Drug must not be subjected to temperature below 40° F --Do not apply to ponds when water is warmer than 80° F, there is a heavy phytoplankton bloom or dissolved oxygen is less than 5 mg/L --Ponds may be retreated in 5 to 10 days if needed -- Do not treat ponds containing striped bass
	Select finfish eggs: salmon, trout, esocid	Control fungi of the family Saprolegniaceae	Select finfish eggs: 1000-2000 ppm for	Preliminary bioassay should be conducted to determine

Appendix C

Drug	Species	Indication	Dosage regimen	Limitations/Comments
Formalin (Parasite-S® by Western Chemical,	All finfish	Control protozoa (Chilodonella, Costia, Epistylis, Ichthyophthirius, Scyphidia, Trichodina spp.) and monogenetic trematodes (Cleidodiscus, Dactylogyrus, Gyrodactylus spp.)	Tanks and raceways: Salmon & trout Above 50°F: up to 170 µl/L; up to 1 hr Below 50°F: up to 250 µl/L; up to 1 hr All other finfish up to --250 µl/L; up to 1 hr Earthern ponds: 15 to 25 µl/L; indefinitely	--Drug must not be subjected to temperature below 40° F --Do not apply to ponds when water is warmer than 80° F, there is a heavy phytoplankton bloom, or dissolved oxygen is less than 5 mg/L --Ponds may be retreated in 5 to 10 days if needed --Do not treat ponds containing striped bass
	All finfish eggs	Control fungi of the family Saprolegniaceae	All finfish eggs: 1000-2000 ppm for 15 min.; Acipenseriformes up to 1500 ppm for 15 min.	Preliminary bioassay should be conducted to determine species sensitivity
	Penaeid shrimp	Control protozoan parasites (Bodo, Epistylis and Zoothamnium spp.)	Tanks and raceways: 50 to 100 µl/L, up to and 4 hours daily; Earthern ponds: 25 µl/L; single treatment	--Drug must not be subjected to temperature below 40° F --Do not apply to ponds when water is warmer than 80° F, there is a heavy phytoplankton bloom, or dissolved oxygen is less than 5 mg/L -- Ponds may be retreated in 5 to 10 days if needed
Sulfamerazine (by Roche Vitamins, Inc.)	Rainbow, brook, and brown trout	Control furunculosis	--10 g/100 lb/day for up to 14 days	--In feed --21 day withdrawal time --Not currently available

Approval applies only to the specific drug which is the subject of a new animal drug application (NADA); active ingredients from other sources (e.g. bulk drug from a chemical company or similar compounds made by companies other than those specified in the NADA) are **not** approved new animal drugs.

Approval applies only to use of the drug for the indications and manner specified on the label.

An INAD exemption is not the same as approval; it merely temporarily permits research (under specific conditions) on anunapproved compound.

This is an abbreviated summary. For complete labeling see the package insert.

Appendix C

B. Low Regulatory Priority Aquaculture Drugs

The following compounds have undergone review by the Food and Drug Administration and have been determined to be new animal drugs of low regulatory priority. The FDA is unlikely to object to the use of these substances if the following conditions are met:

(1) The substances are used for these indications;
(2) The substances are used at the prescribed levels;
(3) The substances are used according to good management practices;
(4) The product is of an appropriate grade for use in food animals, and
(5) There is not likely to be an adverse effect on the environment.

ACETIC ACID	1000 to 2000 ppm dip for 1 to 10 minutes as a parasiticide for fish.
CALCIUM CHLORIDE	Used to increase water calcium concentration to ensure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 10 – 20 ppm $CaCO_3$. Also, used up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish in order to enable fish to maintain osmotic balance.
CALCIUM OXIDE	Used as an external protozoacide for fingerlings to adult fish at a concentration of 2000 mg/L for 5 seconds.
CARBON DIOXIDE GAS	For anesthetic purposes in cold, cool, and warm water fish.
FULLER'S EARTH	Used to reduce the adhesiveness of fish eggs to improve hatchability.
GARLIC (Whole Form)	Used for control of helminth and sea lice infestations of marine salmonids at all life stages.
HYDROGEN PEROXIDE	Used at 250 – 500 mg/L to control fungi on all species and life stages of fish, including eggs.
ICE	Used to reduce metabolic rate of fish during transport.
MAGNESIUM SULFATE	Used to treat external monogenic trematode infestations and external crustacean infestations in fish at all life stages. Used in all freshwater species. Fish are immersed in a 30,000 mg MgSO4/L and 7000 mg NaCl/L solutions for 5 to 10 minutes.
ONION (Whole Farm)	Used to treat external crustacean parasites, and to deter sea lice from infesting external surface of salmonids at all life stages.
PAPAIN	Use of a 0.2% solution in removing the gelatinous matrix of fish eggs in order to improve hatchability and decrease the incidence of disease.
POTASSIUM CHLORIDE	Used as an aid in osmoregulation; relieves stress and prevents shock. Dosages used would be those necessary to increase chloride ion concentration to 10 – 2000 mg/L.
POVIDONE IODINE	100 ppm solution for 10 minutes as an egg surface disinfectant during and after water hardening.
SODIUM BICARBONATE	142 – 642 ppm for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.
SODIUM CHLORIDE	0.5% to 1.0% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock; and 3% solution for 10 to 30 minutes as a parasiticide.
SODIUM SULFITE	15% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability.

Appendix C

C. FDA Approval of New Animal Drugs for Minor Uses and for Minor Species

Otherwise known as MUMS, this "Guidance for Industry" document is intended to provide specific guidance on the means for generating effectiveness and safety data to support the approval of new animal drugs for minor uses and minor species, which includes fish, shellfish, and other aquaculture species; in addition to rabbits, ratites, gamebirds, and small ruminants. It represents the agency's current thinking on drug approval for minor uses and minor species, but does not create or confer any rights for or on any person and does not operate to bind the FDA or public. Alternative approaches may be used if such approach satisfies certain requirements. For questions regarding the MUMS document, contact Meg Oeller, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-7581 (email: moeller@bangate.fda.gov). Additional or updated copies may be requested from the Communications Staff (HFV-12) , Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855 and may be viewed on the Internet at *http://www.fda.gov.cvm.* The FDA has also issued a Compliance Policy Guide on the entitled "Extra-Label Use of Medicated Feeds for Minor Species." The full text of this CPG can be found in the following section.

D. Compliance Policy on Extra-Label Use of Medicated Feeds.

CHAPTER - 6
SUBCHAPTER - 615

Sec. 615.115 Extra-label Use of Medicated Feeds for Minor Species

Introduction

This compliance guidance document (Compliance Policy Guide) is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new Compliance Policy Guide and will be included in the next printing of the Compliance Policy Guides Manual. It is intended for FDA personnel and is available electronically to the public. It represents the Agency's current thinking on extra-label use of medicated feeds for minor species (as defined in 21 CFR 514.1 (d)(1)(ii)). Minor species are defined by exclusion as animals other than cattle, horses, swine, chickens, turkeys, dogs and cats. The document is intended to provide guidance to the field concerning the Agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species. It does not confer any rights for or on any person and does not operate to bind FDA or the public.

Background

Prior to 1994, the Federal Food, Drug, and Cosmetic Act (the Act) did not permit the extra-label use of animal drugs, but the Agency exercised regulatory discretion regarding extra-label use of animal drugs provided certain criteria were met. These criteria were published in Compliance Policy Guide 7125.06 and were largely incorporated into the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). AMDUCA amended the Act to permit extra-label uses under certain conditions. The regulations promulgated pursuant to AMDUCA are codified at 21 CFR part 530.

AMDUCA did not permit extra-label use of medicated feeds. However, there are some minor species that cannot be practically medicated in any way other than through the use of medicated feeds. Furthermore, minor species such as fish and game birds have very few drugs approved for their use. In such situations, a veterinarian may determine that extra-label use of medicated feeds approved for use in other species can prevent suffering and death in these minor species.

Appendix C

Before the implementation of AMDUCA, the Agency occasionally exercised regulatory discretion for extra-label use of medicated feeds for minor species based on a medical need as long as the medicated feeds were formulated and labeled in accordance with their approved application. Because AMDUCA did not permit extra-label use of medicated feeds, the Agency is providing this guidance to our field personnel for use when such extra-label use is encountered.

POLICY

The use or intended use of medicated feeds for treating animals in any manner other than in accordance with the approved labeling causes the drug used in the feed to be adulterated within the meaning of Section 501(a)(5) of the Act and the medicated feed to be adulterated within the meaning of Section 501(a)(6) of the Act. The Agency will consider regulatory action when it finds such use or intended use.

Nevertheless, extra-label use of medicated feed for treatment of minor species may be considered when the health of animals is threatened and suffering or death would result from failure to treat the affected animals. In instances of this nature, the Agency will not ordinarily consider regulatory action against the veterinarian or animal producer provided all of the circumstances listed below exist.

Similarly, the Agency is unlikely to take regulatory action against a feed mill in instances where it produces a properly formulated and labeled medicated feed even though the feed mill may be aware that such feed is intended to be used for an extra-label purpose for minor species. This also presumes that those circumstances listed below that are applicable to feed mills exist. The Agency anticipates that any regulatory action taken based on the extra-label use of a medicated feed for a minor species will be directed at the following:

1. veterinarians who authorize such use in a manner that is inconsistent with this guidance;

2. animal producers who use the feed in a manner that is inconsistent with this guidance;

3. all persons, including veterinarians and animal producers, who promote the feed for extra-label use; and

4. feed mills that manufacture/ distribute the feed in disregard of this guidance.

Under this guidance, the Agency ordinarily will not consider regulatory action if:

1. The medicated feed is used in an extra-label manner only for treatment of minor species as defined in the Code of Federal Regulations (21 CFR 514.1 (d)(1)(ii)). For the purposes of this guidance, "extra-label use" refers to the actual or intended use of an approved medicated feed in a manner that is not in accordance with the approved labeling. Extra-label use includes, but is not limited to:

   - o use in minor species not listed in the labeling,

   - o use for indications (diseases or other conditions) not listed in the labeling, and

   - o deviation from the labeled withdrawal time;

2. The medicated feed is approved for use in a major species animal and is formulated and labeled according to its approved labeling as described in the Code of Federal Regulations (21 CFR part 558). The nutrient content and formulation are in accordance with use in the approved major species. The labeling reflects the approved use in dosage, formulation, and nutrient content;

3. The medicated feed is to be used in a food-producing minor species and the feed is approved in a major food-producing species;

4. Extra-label use of medicated feed in aquaculture is limited to medicated feed products approved for use in aquatic species;

5. Extra-label use of medicated feed is limited to farmed or confined minor species. Use for the treatment of unconfined wildlife is not appropriate under this policy;

6. The medicated feed is used in an extra-label manner only with the express prior written recommendation (see part 8.h. of this guidance) and oversight of an attending licensed veterinarian within the context of a valid veterinarian-client-patient relationship. A valid veterinarian-client-patient relationship is defined as one in which:

    a. a veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (the owner or other caretaker of the animal(s)) has agreed to follow the instructions of the veterinarian;

    b. the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept;

    c. there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

    d. the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

7. Extra-label use is limited to therapeutic treatments when the health of an animal is threatened and suffering or death may result from failure to treat. It is inappropriate under any circumstances to use a medicated feed in an extra-label manner for improving rate of weight gain, feed efficiency, or other production purposes;

8. The veterinarian has:

    a. made a careful diagnosis and evaluation of the conditions for which the drug is to be used;

    b. made a determination that there is no approved new animal drug that (i) is labeled for such use, and (ii) contains the same active ingredient which is in the dosage form and concentration necessary for treatment;

    c. made a determination, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug, if any, is clinically ineffective for its intended use;

    d. ascertained that there is no therapeutic dosage form that can be practically used under legal extra-label use;

    e. established a withdrawal period that is substantially extended beyond that of the approved use (supported by appropriate scientific information) prior to marketing of milk, meat, eggs, or other edible products derived from the treated minor species, if applicable;

f. instituted procedures to assure that the identity of treated animals is carefully maintained;

g. taken appropriate measures to assure that assigned timeframes for withdrawal are met and no unsafe drug residues occur in any food-producing animal subjected to extra-label treatment;

h. made a written recommendation that includes the medical rationale (e.g., diagnosis, drug selection, dose and duration, and the required withdrawal period), dated within 3 months prior to use. The animal producer and the veterinarian have kept copies and make them available to the FDA upon request; and

i. has reported any adverse reactions to FDA within 10 days of occurrence (1-888-FDA-VETS).

9. The animal producer has:

a. kept complete and accurate records of feeds received, including labels, invoices, and dates fed. These records are kept for at least 1 year from the date of delivery;

b. kept a current copy of the veterinarian's written recommendation for the extra-label use of the medicated feed;

c. instituted procedures to assure that the identity of treated animals is carefully maintained;

d. taken appropriate measures to assure that assigned timeframes for withdrawal are met and no unsafe drug residues occur in any food-producing animal subjected to extra-label treatment;

e. used the medicated feed in accordance with federal, state, and local environmental and occupational laws and regulations. This is especially important for aquaculture uses;

f. met the requirements of the federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any requirements applicable to ground-water pollution. The producer should contact the offices responsible for issuing NPDES permits, and other similar permits, to be certain they have no objection to the use and release of the drug; and

g. followed user safety provisions as set forth in approved product labeling to protect individuals who may be exposed to the drug.

Regulatory Guidance

In instances where the above circumstances do not exist, the following regulatory steps may be taken. A Warning Letter is ordinarily the first choice of action. The following language should be used to cite the violation:

The animal drug **** is adulterated within the meaning of Section 501(a)(5) as its use or intended use does not conform to its approved application in accordance with Section 512(a)(1)(B).

The animal feed **** is adulterated within the meaning of Section 501(a)(6) as its use or intended use does not conform to its approved application in accordance with Section 512(a)(2)(C).

If a veterinarian did not recommend the use of the feed for extra-label purposes, the Warning Letter should be issued to the animal producer with a copy sent to the veterinarian, if any. If a veterinarian recommended the use of the feed for extra-label use other than as described above, the Warning Letter should be issued to the veterinarian with a copy sent to the animal producer.

If the feed is not formulated and labeled in accordance with approved conditions of use as described in the Code of Federal Regulations, a Warning Letter should be issued to the feed mill, with a copy to the animal producer or veterinarian, if any.

The feed mill also may be considered for regulatory action if there is sufficient evidence to show that it knew that the feed was intended for extra-label use in other than a minor species.

If there is a tissue residue violation, the District should establish the responsible individuals. This would ordinarily be the animal producer and/or veterinarian if not covered under the circumstances of this policy. However, in rare situations such as documented misformulation or no approval in 21 CFR part 558, the feed mill may be considered responsible for the violation.

The following language should be used to cite the tissue residue violation:

> A (type of animal) sold for food on or about (date) is adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Food, Drug and Cosmetic Act. Analysis of tissues disclosed the presence of the drug (level and name of drug for each tissue in which illegal residue was reported.) There is no tolerance for this drug in the edible tissues of (type of animal). Our investigation revealed that you are responsible for this violation. Should field personnel have any questions about the application of this guidance, they may call CVM's Division of Compliance, Drugs and Device Team at (301) 827-0150.
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> Issued: 04/18/2001

Contact Information

Agency	Website	Telephone #
New Jersey Department of Agriculture, Office of Aquaculture Coordination	*www.state.nj.us/agriculture*	(609) 984-6757
New Jersey Department of Agriculture, Division of Animal Health, State Veterinarian		(609) 292-3965
NJDEP Fish & Game, Freshwater Fisheries	*www.state.nj.us/dep*	(609) 292-1599
NJDEP Division of Water Quality		(609) 633-7021
NJDEP Marine Fisheries		(609) 748-2020
NJDEP Office of Land Use	*www.nj.gov/dep/landuse/*	
State Agriculture Development Committee		(609) 984-2504
USDA- Natural Resources Conservation Service	*www.nrcs.usda.gov*	(732) 246-1171
USDA/Animal and Plant Health Information Service	*www.aphis.usda.gov*	(202) 720-5193 (Dr.Otis Miller)
The Pinelands Commission		(609) 894-7300
New Jersey Department of Health and Senior Services	*www.state.nj.us/health*	(609) 588-3123
Food and Drug Administration	*www.fda.gov/cvm/default.html*	
Office of International Epizootics	*www.oie.int*	
Interstate Shellfish Sanitation Conference	*www.issc.org*	

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