

Justification and Scope of Services for a Vaccine, VFD and ELU Contract

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Justification

The management of fish diseases in the Pennsylvania Fish and Boat Commission's (PFBC) State Fish Hatcheries and Cooperative Nurseries is essential to producing the millions of fish that are expected each year. One of the goals of all State Fish Hatcheries and Cooperative Nurseries should be the prevention of disease through Best Management Practices (BMP), including the use of vaccines. Even with the application of appropriate BMPs, fish within the PFBC's State Fish Hatcheries and Cooperative Nurseries are often diagnosed with and treated for diseases. Because the fish are being released into the Commonwealth's waters, they have the potential to be consumed, and therefore, all treatments of these potential food fish fall under the regulatory authority of the US Food and Drug Administration (FDA). Some treatments are approved by the FDA for general use, as long as criteria on the label are met. Other treatments require that they be prescribed and administered under the supervision of a licensed veterinarian; these include Veterinary Feed Directives (VFD) and Extra Label Use (ELU) options.

Vaccines- When used correctly, vaccines can be administered to large numbers of fish in a cost-effective manner. The PFBC's use of all vaccines is regulated by the FDA and there are a limited number of facilities that can produce the vaccines needed by the PFBC. There are several commercially available vaccines for specific bacterial pathogens such as *Aeromonas salmonicida*. However, having the ability to produce autogenous vaccines that are specific to the genetic strains of bacterial pathogens found at a single or multiple hatcheries is advantageous to the PFBC. The use of vaccines as a preventive measure can greatly reduce and or eliminate the loss of fish and the associated cost of treatment.

Veterinary Feed Directives- The FDA requires a VFD be provided to the feed mill or feed distributorship prior to the distribution of and treatment with certain antibiotics. The PFBC State Fish Hatcheries and Cooperative Nurseries need to have the ability to use these antibiotics to ensure that fish can be raised in the most efficient way possible. The PFBC and Cooperative Nurseries will need VFDs for the following antibiotics;

1. **Oxytetracycline Dihydrate** (Terramycin® 200F for Fish)
2. **Sulfadimethoxine & Ormetoprin** (Romet® TC)
3. **Florfenicol** (Aquaflor®)

Furthermore, the ability to treat fish using these antibiotics reduces the chance of releasing or stocking diseased fish into the waters of the Commonwealth.

Extra Label Use Prescriptions- The FDA allows for off-label use of some chemicals and drugs. This is allowed if the treatment is administered under the guidance and prescription of a licensed veterinarian and is used following the treatment regime that is approved by the FDA for a different species and or disease/condition. Due to the limited label approved treatment options available and restrictive effluent permit limits, the PFBC will often need to treat fish using an ELU prescription from a veterinarian.

Scope of Services

- I. **Vaccine:** Vaccines should be made by a US Department of Agriculture Licensed facility that is approved to manufacture autogenous vaccines. The vendor should also have the ability to manufacture vaccines through a prescription by a veterinarian with a valid PA license.
 - a. Vaccines will either be hatchery specific or a trivalent/bivalent mix from bacterial isolates provided to the manufacturer by the PFBC.
 - i. The vendor must have the capability to store and archive isolates for future use and provide additional characterization of the isolates if needed.
 - ii. The PFBC will provide bacterial cultures annually to the vendor.
 - b. The vendor will charge per liter of vaccine delivered.
 - c. The vendor should be able to produce up to 200 liters of vaccines annually and provide the product within 2 months of the request.

- II. **Veterinary Feed Directives for PFBC State Fish Hatcheries and Associated PFBC Cooperative Nurseries:** Annually provide the Pennsylvania Fish and Boat Commission's State Fish Hatcheries and Cooperative Nurseries with Veterinary Feed Directives in compliance with the FDA's regulations. A VFD is good for 6 months, and as a result, 2 VFDs would be needed for each antibiotic used in a fiscal year.
 - a. The vendor will charge a fee for each VFD. Each VFD will cover the therapeutic use of a specific antibiotic. Each VFD can be used for multiple treatments at the PFBC State hatcheries and associated Cooperative Nurseries.
 - i. The fee will include the cost associated with establishing and or maintaining a veterinarian client relationship required to issue a VFD.
 - b. The vendor will provide the feed distributorship or feed manufacturer with an electronic copy of the VFD within 2 working days of an acceptable diagnosis and treatment recommendation.
 - c. The vendor will provide a clear definition of an acceptable diagnoses and any documentation of treatment that will be needed.

- III. **Extra Label Use Prescriptions:** Annually provide the Pennsylvania Fish and Boat Commission with prescriptions for treatments that are categorized as Extra Label Use by the FDA.
 - a. The vendor will charge an annual fee for each ELU prescription.
 - i. Each prescription will cover multiple treatments at multiple facilities.

- ii. The fee will include the cost for establishing and or maintaining a veterinarian client relationship.
- b. The vendor will provide a clear definition of an acceptable diagnoses and any documentation of treatment that will be needed.
- c. The vendor must be available to provide this service for up to 10 different treatments and treatment regimes.