Summary of Findings of the National Aquaculture Association's Survey of Broodstock in Aquaculture and Drug Indexing

Submitted by Craig Watson

University of Florida, Institute of Food and Agricultural Sciences

Tropical Aquaculture Laboratory

Introduction

The National Aquaculture Association (NAA) and the Food and Drug Administration's Center for Veterinary Medicine (CVM) began discussions on the opportunity to allow indexing of drugs for non-food life stages of food species where there was a reasonable certainty that the animal being treated would not be used as human food, nor fed to another food-producing animal. Beyond early life stages, broodstock were identified as a group of animals that currently meet, or could meet these criteria if indexing was available. While early investigations by the author and others had indicated this was true, a more formal, national survey was suggested to provide additional assurances before moving forward. Together, NAA and CVM developed a series of questions that was intended to identify species in aquaculture, potential compounds that might be used, number of animals involved, practices to delineate broodstock from other animals on the farm, and whether broodstock ever entered the human food chain. In addition, there were concerns that label restrictions alone may not fully assure compliance, so the survey also included questions about extension and outreach, and other permits, certifications, or regulations that might reinforce an index label. The survey is attached as Appendix I.

Methods

The final survey included eight main questions, several of which included sub-questions. It was distributed nationally by the NAA to all of its members, the Association of Fish and Wildlife Agencies, the US Fish and Wildlife Service (USFWS), the US Department of Agriculture (UADS) maintained "Aquacontacts" list serve, and subsequently was forwarded by several other state associations. The survey was conducted between April 27th and May 22nd, 2020. All responses were returned electronically to the author. A few of the surveys were completed by extension and research faculty on behalf of the clientele they work with, representing a much large group of producers (e.g., Mississippi and Alabama catfish farms). All returned surveys have been

treated as confidential, with names and association of respondents redacted from the results. A total of 38 completed surveys were returned.

Results

The following states are represented in the survey results:

Alabama, Alaska, Arkansas, California, Colorado, Florida, Idaho, Mississippi, Nevada, New York, Oregon, and Washington.

Question 1. What species of fish do you house in your facility?

The survey identified the following 39 species of fish in production:

Atlantic Pinfish

Atlantic Salmon

Atlantic Spot

Blue Catfish

Bluegill

Black Crappie

Brook Trout

Brown Trout

Channel Catfish

Chinook Salmon

Chum Salmon

Cobia

Coho Salmon

Cutthroat Trout

Fathead Minnows

Flathead Catfish

Golden Rainbow Trout

Golden Shiners

Grass Carp

Largemouth Bass

Muskellunge

Ornamental fish

Pink Salmon

Pompano

Rainbow Trout

Red-ear Sunfish

Red Drum

Steelhead Trout

Striped Bass

Sockeye Salmon

Southern Flounder

Spotted Sea Trout

Threadfin Shad

Tilapia

Tiger Trout

Triple Tail

Walleye

White Bass

White Crappie

a) Approximately how many fish are housed at your facility and how many are considered broodstock?

   Responses varied significantly on the total number of fish from a low of 3,500 to a high of 40,000,000 with an average number being 4,535,962. Total designated as brood stock also varied significantly from a low of 90 to a high of 200,000 with an average number being 49,765. The percent of fish designated as broodstock varied from a low of 0.004%, to a high of 42%. These figures do not include those farms which only house broodstock – i.e., salmonid farms producing eyed-eggs as their sole product.

Question 2. What defines a broodstock fish?

Broodstock fish were always defined as fish used for reproductive purposes.

a) When in its lifetime, is a fish identified as broodstock?

This question varied in response significantly with some hatcheries identifying and designating broodstock at fertilization of the egg, to others when adult fish swam into their facilities. Age to sexual maturity also varied significantly from $\leq$ 1 year to 5+ years of age.

Question 3. How are broodstock identified at your facility?

Broodstock were identified by a wide range of methods, from wild-collected animals simply of the appropriate size and/or age, to genetic analysis of fertilized eggs. Family performance records was a common criterion for selecting fish as broodstock. Broodstock were often identified from other fish due to their location (i.e., they are housed separately). Many respondents included that individual animals are identified with pit tags.

a) Are broodstock fish housed separately (by room, pond, or water supply) from non-broodstock fish?

Except for facilities where broodstock were the only fish on the facility the unanimous answer to this question was yes, with some answers containing a hybrid of the two – i.e., broodstock, once identified were removed to a separate facility.

b) If they aren't housed separately, would it be difficult for you to house them separately or insure they are not mingled with non-broodstock fish?

The unanimous response was N/A.

Question 4. What drugs would be useful for broodstock treatment and management (e.g. releasing hormones, sedatives/anesthesia, steroids, antibiotics?

The following categories of compounds were identified in their order of times they were listed, with the first being the most times they were listed.

Releasing hormones

Anesthetics/sedatives

Antibiotics

Steroids

Anti-parasitic treatments

Question 5. What is the normal procedure for disposal/disposition of broodstock after they are spawned?

Many of the species are kept on site for multiple spawning events. While some broodstock are released after spawning, most are used on site until they die.

a) For fish spawned over multiple years, what is their ultimate fate?
   The most common response is that they are sent to a landfill, buried on site, or sent to a fertilizer rendering plant. Only a few stated that they are subsequently released, and all of those respondents were from public hatcheries. Catfish farms reported that some broodstock are used as food, but rarely.
b) If a fish survives the spawning event, would it ever revert back to being a "non-broodstock" fish?
   The unanimous response was no.

Question 6. Specifically, are broodstock fish ever used as human food directly, released where they might be captured and consumed, or fed to other food-producing animals?

The majority of responses said no, but there were responses that said they would occasionally/rarely be sold as food, released into the wild, or donated to food banks. One state hatchery system reported that all fish are ultimately released, including those used as broodstock.

a) If so, is this common practice or only occasional (e.g. stocking brood fish for fishing derbies)?
   Except for one state program that releases every fish, this was rare or occasional. Several public hatcheries commented that any fish released are not eligible for capture and subsequent consumption because of their location (no fishing allowed), size (above a legal slot size), or their species (closed to any take).
b) Could any such practices easily be stopped in exchange for the legal access of drugs for broodstock through the indexing process?
   Except for the same above-mentioned state hatchery program that releases everything, the unanimous answer was yes, often accented with the word "easily".
c) Are records kept to designate and trace broodstock at the facility?
   The unanimous answer was yes.

Question 7. What other state or federal permits or regulations, or third-party certifications exist for farms that regulate the use of drugs and chemicals beyond the FDA label (e.g.

Environmental Protection Agency (EPA) discharge permitting or other discharge permits, FDA Seafood HACCP guidelines or other processing plant restrictions, operating licenses/permits, third-party certifications such as Global Aquaculture Alliance Best Aquaculture Practices (BAP), etc.) and what enforcement actions or penalties might a producer be subject to if they were to violate an FDA drug label?

Global Aquaculture Alliance and BAP certification was mentioned by several of the private hatcheries.

EPA discharge permitting and discharge monitoring was mentioned by both private and public hatcheries.

State aquaculture licenses or certificates was listed by private hatcheries.

Food Safety Inspection Service (FSIS) program for the channel catfish industry was identified.

FDA HACCP was identified by private producers.

USFWS and other state agency hatchery guidelines/rules were identified

Veterinarian licensure was listed.

Several respondents said they did not know of anything.

Question 8. What extension or other educational programs and/or materials exist that educate farms in your state on the legal use of drugs and chemicals?

National and State Sea Grant programs
State fish and wildlife agencies
Land Grant Universities/Cooperative Extension Service
USFWS Short Courses
FDA CVM
USFWS AADAP
State Department of Health
State Department of Ecology
A Fish Veterinarian with a valid veterinarian-patient-client relationship
USDA Aquaculture Permitting and Production Reporting System (an Agricultural Research Service Program)
Regional and state fish health labs
State and Federal Aquaculture Labs/Centers

Summary

This survey was an attempt to get a wider and more formal representation of broodstock in aquaculture in the United States, specifically focused on whether they are currently in the human food chain, and if so, could they be removed from it. The other question was to determine what other factors may play in providing additional assurances that a Food and Drug Administration (FDA) label restricting use for only non-food animals would be complied with.

Not surprisingly, the preponderance of the responses came from public programs involved in stock enhancement, endangered species work, and/or aquaculture research. This is in large part due to the fact that leadership in many of these agencies directed their staff to cooperate in the survey. While the response from private hatcheries was smaller, there were responses from representatives of the major species in commercial food fish production (i.e., catfish, trout, salmon, and tilapia). Responses were received from 11 states, reporting on activities with 39 different species of fish.

The definition of broodstock in aquaculture is well understood and universally accepted – i.e., fish used for reproduction of more fish. The age and size of a fish when it is designated as a broodstock animal varies significantly based on the species and the hatchery goals, but all hatcheries house their broodstock separately from fish destined for consumption, some on separate facilities. Much of the commercial salmonid industry uses the latter model, meaning that production of food animals is performed on separate farms, often by different companies buying their seed from the hatcheries that only contain broodstock. Hybrid striped bass, tilapia, and catfish also rely heavily on hatcheries that only produce fingerlings, and separate farms grow the fish for sale as a food product. Where broodstock and food animals are produced on the same facility, only a small percentage are designated as broodstock.

Broodstock are not typically used as food animals for various reasons. Several respondents noted that their use of pit tags eliminate any opportunity to send the fish to a processor. Others noted that the size and condition of the fish after spawning made them unsuited for food. All commercial hatcheries stated that they did not normally allow broodstock to enter the human food chain, and for those rare occasions where they do, they could easily stop the practice if indexed therapeutants became available.

The most common occasion for a broodstock fish entering the human food chain comes from public hatcheries which will sometimes release fish after spawning, or donate them to Tribes, other agencies, or food banks. Mitigating factors to human consumption were also noted for some releases as the fish were released into waters where fishing was prohibited, the species was threatened or endangered and therefore catch was prohibited, or the size of the brood stock was above a maximum legal slot limit. Those respondents indicated that they could stop that practice if it meant having access to indexed products.

As an extreme outlier, one response, from an entire state hatchery program, indicated that they stock every fish back into the water, and that changing that procedure was not acceptable.

While most respondents clearly understood the question on overlying regulations or other factors that would assist in enforcing compliance with a federal FDA index label, it was answered with an "I don't know" type response by some, even though they are clearly regulated internally – i.e., they work for state and federal hatcheries. All the private hatcheries responded with various state, federal, or third-party certifications which regulate food products either directly (e.g., HACCP, FSIS, GAA BAP), or indirectly based on allowable drugs and chemicals for the farm (e.g., NPDES permits, state aquaculture certificates/permits, veterinary prescription requirements, etc.). It was clear that among public agency hatcheries, internal policy and inspection (e.g., IACUC, "agency standards") had influence over drug usage.

There is a wide and varied list of educational and informational sources that hatcheries use to determine what practices. All respondents listed multiple sources for information and educational resources concerning drug usage and labeling.

Conclusion/Discussion

The survey confirmed that broodstock fish in US aquaculture are well defined, labeled, tracked, and monitored in all cases. They are housed separately from animals which would enter the human food chain directly or by being used as food for another food-producing animal. There is very little to any value to broodstock fish as a food animal, compared to their value as seed production for future crops of animals. In all but one case within a state wildlife agency, practices can easily be put in place to eliminate the rare occasions where broodstock fish are purposefully used as food, or released where they might subsequently be captured and consumed. Where broodstock are rendered, it is for fertilizer, not to be used as an animal feed ingredient.

Overlapping regulations, permits, and certifications that regulate use of drugs and chemicals on fish farms exist throughout the country, but may vary depending on the location and species of fish being produced. Multiple, highly reputable sources for getting information on drug use and regulations were identified, all of which could be used to strengthen the message that any potential index label for broodstock fish treatments would depend on that fish never being allowed to enter the human food chain. Existing regulations, especially FDA Seafood Hazard Analysis Critical Control Point (HACCP) guidelines[1] identify aquaculture drugs as a hazard mitigated by conforming to drug and chemical labeling to prevent illegally treated fish from entering the food market. Seafood processors purchasing farm-raised fish are required to implement:

[1] FDA. 2020. Chapter 11, Aquaculture Drugs *in* Fishery and Fishery Products: Hazards and Controls Guidance, Fourth Edition. HHS, FDA, CFSAN, Office of Food Safety. (https://www.fda.gov/media/80637/download accessed June 1,2020)

"Preventive measures for the hazard of aquaculture drugs used in aquaculture operations and during live transportation can include:

• Conducting on-farm visits to review drug usage (other than INADs) before receipt of the product, coupled with a supplier's certificate that any INADs used were used in conformance with the application requirements and appropriate verification;

• Reviewing, at time of receipt, drug usage records (other than INADs), coupled with a supplier's certificate that any INADs used were used in conformance with the application requirements and appropriate verification;

• Reviewing, at time of receipt, the producer's lot-by-lot certification of proper drug usage, including INAD usage, coupled with appropriate verification;

• Conducting, at time of receipt, drug residue testing;

• Reviewing, at time of receipt, evidence (e.g., a third-party certificate) that the producer operates under a third party-audited Quality Assurance (QA) program for aquaculture drug use (page 189)."

For larger facilities which require a National Pollution Discharge Elimination Permit (NPDES) permit, the language is explicit on drugs. Public or private aquaculture production facilities that exceed production and discharge criteria defined in the Clean Water Act must acquire a NPDES permit from a delegated state agency or the US Environmental Protection Agency. The agency provides a guidance document for permit writers and facility operators entitled, *Compliance Guidance for the Concentrated Aquatic Animal Production Point Source Category*.[2] Implicit to the EPA regulations is acceptance that FDA approved drugs will be used in conformance to the label. The Guidance describes effluent limitation guidelines that contain general reporting requirements for the use of certain types of drugs. All concentrated aquatic animal production facilities that are subject to 40 CFR 451 must notify the permitting authority of the use of any investigational new animal drug (INAD) and any extralabel drug use where the use may lead to a discharge to waters of the United States. Chapter 6 of the Guidance requires reporting of the use of INAD and extralabel drugs and provides the reporting forms for use by the facility operator.

At the state level, many permits and certificates of operation also include restrictions on the use of drugs and other chemicals. As an example, State of Florida aquaculture facility regulations, referred to as Best Management Practices, are required for certification (i.e., permitting) of a commercial aquaculture facility (i.e., anyone that cultures and sells an aquatic animal and plant are required to become certified) states:

[2] EPA. 2006. Compliance Guidance for the Concentrated Aquatic Animal Production Point Source Category. Engineering and Analysis Division Office of Science and Technology U.S. Environmental Protection Agency Washington, DC 20460 (https://www.epa.gov/sites/production/files/2015-11/documents/caap-aquaculture_compliance-guide_2006.pdf accessed June 2, 2020).

C. DRUG USAGE AND HANDLING

There is a limited number of Food and Drug Administration (FDA) approved drugs and therapeutants available to treat aquatic animals. For current information, contact a licensed veterinarian or visit the Aquatic Animal Drug Approval Partnership website at: http://www.fws.gov/fisheries/aadap/home.htm.

Best Management Practices:

• All drugs, therapeutic substances, and antibiotics must be used, applied, stored, or disposed only as directed by an FDA approved product label or as prescribed by a Florida licensed veterinarian.

• Drugs may not be used or prescribed for extra-label use when the drug label prohibits extra-label use.

• Maintain a log of drug usage at the facility. [3]

Hatcheries may also subscribe to private, third party organizations to gain access to buyer and consumer directed identifiers and educational information to assure them of environmentally and socially responsible production. Successful certification requires implementation of described management standards and periodic compliance audits. Examples of these eco-labels and programs include Global GAP (https://aquaculture.ggn.org/en/the-globalg-a-p-standard-for-aquaculture.html) and Global Aquaculture Alliance BAP (https://www.bapcertification.org/Standards). Both programs require compliance with drug and chemical labeling and associated regulations.

[3] FDACS. 2016. Aquaculture Best Management Manual November 2016. Florida Department of Agriculture and Consumer Services, Division of Aquaculture. Tallahassee, Florida (https://www.fdacs.gov/content/download/64045/file/BMP_Rule_and_Manual_FINAL.pdf accessed June 2, 2020).

Appendix I

Broodstock and Drug Indexing Survey
National Aquaculture Association

Introduction

The National Aquaculture Association is requesting information about the management of broodstock fish. This information will be submitted to the US Food and Drug Administration's Center for Veterinary Medicine (CVM) to support the possibility of expanding eligibility for indexing of products for use in some fish species where there is a reasonable certainty that the animal will not be consumed by humans or other food-producing animals. Indexing is a process developed within the Minor Use Minor Species Animal Health Act of 2004 that provides legal access and sales of unapproved products for non-food animals. It is a much faster and less expensive way to make products available compared to full approval through the new animal drug approval process.

Historically, indexing was only available for species that were not members of a food animal species (with the exception of non-food early life stages such as oyster larvae or some fish eggs), such as ornamental fish. CVM has now said they are willing to entertain that there may be animals within a food species that are not used for food, and thus may be eligible for indexing. This represents a significant change in policy for indexing and requires appropriate assurance that fish treated with indexed products have a reasonable certainty that they will not enter the human food chain. Broodstock have been identified as one group of fish that are typically not eaten or fed to other food-producing animals. For additional information, visit the FDA CVM webpage dedicated to drug indexing: https://www.fda.gov/animal-veterinary/minor-useminor-species/drug-indexing.

While specific index label restrictions are one method for assuring that no animals being treated will enter the human food chain, CVM is also seeking information that would provide additional assurances that an indexed product used in broodstock fish will not find its way into the human food chain

Below is a list of questions that have been developed to provide the information needed to accomplish this. Information provided will be held confidential. Please provide any and all information you can to each question and return it to Craig Watson, Director, University of Florida, Tropical Aquaculture Laboratory, at cawatson@ufl.edu by May 5th. If you need any further information, please contact me by email or cell phone 813-505-2625.

1. What species of fish do you house in your facility?
    a. Approximately how many fish are housed in your facility and how many are considered broodstock?
2. What defines a broodstock fish?

    a. When, in its lifetime, is a fish identified as broodstock?
3. How are broodstock fish identified at your facility?
    a. Are the broodstock fish housed separately (by room, pond or water supply) from non-broodstock fish?
    b. If they aren't already housed separately, would it be difficult for you to house them separately or ensure they aren't mingled with non-broodstock fish?
4. What drugs would be useful for broodstock treatment and management (e.g., Releasing hormones, sedatives/anesthesia, steroids, antibiotics)?
5. What is the normal procedure for disposal/disposition of broodstock after they are spawned?
    a. For fish spawned over multiple years, what is their ultimate fate?
    b. If a fish survives the spawning event, would it ever revert back to being 'non broodstock'?
6. Specifically, are broodstock ever used as human food directly, released where they might be captured and consumed, or fed to other food-producing animals, including rendered remains?
    a. If so, is this common practice or only occasional (e.g., stocking brood fish for fishing derbies.)?
    b. Could any such practices easily be stopped in exchange for the legal access of drugs for broodstock through the indexing process?
    c. Are records kept to designate and trace broodstock at the facility?
7. What other state or federal permits or regulations, or third-party certifications exist for farms that regulate the use of drugs and chemicals beyond the FDA label (e.g. NPDES or other discharge permits, HACCP guidelines or other processing plant restrictions, operating licenses/permits, third-party certifications such as Global Aquaculture Alliance BAP, etc.) and what enforcement actions or penalties might a producer be subject to if they were to violate an FDA drug label?
8. What extension or other educational programs and/or materials exist that educate farms in your state on the legal use of drugs and chemicals?