

Fish Health Section



FHS NEWS

Fish Health Section website: <https://units.fisheries.org/fhs/>

Fish Health Section Facebook Site: <https://facebook.com/FishHealthSectionAFS>

Members of the FHS:

Earlier this year, the U.S. Food and Drug Administration (FDA) published [Draft Guidance for Industry \(GFI\) #61, Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species](#) in the Code of Federal Regulations. This draft guidance is intended to replace the previous GFI #61 issued in April 1999 (with a minor update in May 2008).

In the USA, only drugs approved by the FDA are legal for use in aquaculture, including fish raised as food, for fisheries management/conservation, or for other purposes. All fish are considered "minor species", and the new draft guidance sets forth FDA's general expectations for the development and approval of aquaculture drugs. Importantly, this document will establish typical data requirements, i.e., the number and type of studies needed to prove the safety and effectiveness of an aquaculture drug before it can be approved for use. Although aquaculture drug approval research is a narrow subdiscipline of fisheries science, virtually all fisheries professionals are affected--directly or indirectly--by access to safe and effective therapeutants, sedatives, spawning aids, and marking agents for use in fish.

FDA has requested public comments regarding the draft guidance as part of the required public comment period, which ends January 11, 2020. As an AFS-FHS member, this is your opportunity to have your voice heard, and to help shape the process by which aquaculture drugs are approved in the USA. Attached are a series of comments developed by Jesse Trushenski (FHS PPDC member and Past President of AFS) and reviewed by the FHS Policy and Position Development Committee. These comments are being provided to the FHS membership for their information or use (as-is or in a modified form) in providing their own response to FDA. Please note that these comments should not be interpreted as official opinions, positions, or policies of the AFS-FHS at large. If you agree with what is outlined below, please join us in providing FDA with this important feedback by **Jan 11, 2021**.

There are two ways to submit comments to FDA:

Electronic comments can be submitted via the Federal eRulemaking Portal. Go to <https://beta.regulations.gov/document/FDA-1997-D-0444-0021>, and follow the instructions for submitting comments.

If you are unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All comments should be identified with this document's docket number (FDA-1997-D-0444) and are due Jan 11, 2021.

MEETINGS, WORKSHOPS AND COURSES

Joint Meeting of the Northeast Fish Health Committee and AFS Fish Health Section

Burlington, VT

July 12th – 15th, 2021

Go to the [website](#) for more information.

Calling all Aquaculture America 2021 attendees!

Are you interested in speaking in a special session at Aquaculture America 2021, to be held in San Antonio, Texas from August 11th-14th, 2021? Please see the link below to learn more about the National Aquaculture Association (NAA) special sessions that AADAP is co-hosting with the Aquatic Drug Approval Coalition (ADAC) and the Association of Fish and Wildlife Agencies-Drug Approval Working Group (AFWA-DAWG).

<https://www.fws.gov/fisheries/aadap/Expert-Presenters-Invited-Aquaculture-America-2021.html>

JOBS/GRADUATE ASSISTANTSHIPS

Feedtech Proessing Engineer

The Center for Aquaculture Technologies

Souris, Prince Edward Island

Closes: **December 29th, 2020**

Link: <https://aquatechcenter.com/career/feedtech-processing-engineer-souris-pei/>

The Center for Aquaculture Technologies, a private aquaculture innovation, and research company, is seeking a Processing Engineer to assist in the daily operations of its FeedTech Facility in Souris, PE. This is a full-time, permanent position and will begin with the successful candidate reporting to the FeedTech Centre Manager.

Job Duties and Responsibilities:

- Ensuring efficient manufacturing and continuous improvement of all processing products and processes (commercial production and R&D projects),
- Developing, implementing, and managing a preventative maintenance program for the extrusion line,
- Informing the decision-making regarding the processing operation, including effective scheduling, labor utilization, material utilization, and operational improvements,
- Ensuring that product quality, employee safety, and feed safety standards, as well as regulatory requirements, are met or exceeded,
- Supporting the processing operation (production, maintenance, and sanitation) toward the accomplishment of plant & corporate goals, including continuous improvement in quality, feed safety, employee safety, and manufacturing efficiencies.

Experience/Requirements:

Candidates must have a minimum of 3 -10 years of food/feed manufacturing experience, including:

- Education and/or experience that include an Engineering or Bachelor's degree and 3+ years of hands-on experience, preferably in feed/food-related plant operations or equivalent combination of education and experience,
- Operational knowledge of equipment design, installation, operation, using project management and engineering or food/feed technology skills,
- Thorough knowledge of food/feed manufacturing processes and operations,
- Thorough knowledge of material control and operation, including operation of PLC controlled equipment,
- Excellent leadership, planning and communication skills,
- Knowledge and experience with regulatory requirements in the feed sector,
- Experience working within quality management systems and working with SOP's,
- Computer proficiency including Excel, Word, and other software.

The preferred candidate will have strong engineering skills and a keen eye for process optimization.

Key Qualifications:

- Must be eligible to work in Canada.
- Physically able to handle tasks that could include lifting, bending, and climbing.
- Ability to work as part of a team in compliance with facility standard operating procedures.
- Demonstrable organizational skills with the ability to multi-task.
- Self-motivated with a demonstrated ability to think creatively and solve problems.
- Fosters a positive work environment congruent with the company values and philosophy.
- Demonstrable commitment to CAT's Core Purpose: We are driven by the transformative potential of aquaculture. To feed the world, support the environment, and sustain the planet. Our purpose is to unlock this potential.

CATC offers a competitive salary and benefits including group health care and retirement savings plans.

PhD Studentship EASTBIO

Moredun Research Institute/University of Stirling, Institute of Aquaculture

Scotland, UK

Closes: 6 January 2021

Link: <https://www.moredun.org.uk/careers/phd-studentship-eastbio-04-11-20>

EASTBIO: Advancing control of sea lice (*Lepeophtheirus salmonis*) through development of sea louse *in vitro* assay systems

The role:

The successful candidate will develop *in vitro* culture/feeding assay systems that will serve both to reduce the number of fish used in sea lice research and provide novel *in vitro* research and bioassay approaches.

The studentship will be registered at the Institute of Aquaculture (IoA), University of Stirling, will be mainly based at Moredun Research Institute (MRI), but will be expected to work closely with the supervisory team at IoA. The student will also be required to undertake an industrial placement with the Aquaculture team at Moredun Scientific Ltd (MSL). This project will provide the student with a strong background in *in vitro* culture methods, 3D cell culture and bio-imaging, and sea lice biology and culture.

Experience required:

Candidates should have (or expect to achieve) a minimum of a 2:1 Honours degree, or the equivalent qualifications gained outside the UK, in a relevant subject.

Candidates with a background in Aquaculture are especially encouraged to apply.

Funding notes:

This 4 year PhD project is part of a competition funded by EASTBIO BBSRC Doctoral Training Partnership <http://www.eastscotbiodtp.ac.uk/how-apply-0>. This opportunity is open to UK and International students and provides funding to cover stipend and UK level tuition (Unfortunately we are unable to provide funding to cover the difference in fees). Please refer to UKRI website and Annex B of the UKRI Training Grant Terms and Conditions for full eligibility criteria.

We can only accept applications from individuals who have the right to work in the UK.

See attached pdf for more information.

Fish Health Veterinarian

Department of Fisheries & Oceans Canada, AMD and SEP

Courtenay and Nanaimo, Vancouver Island, British Columbia

Fisheries and Oceans Canada (DFO) is hiring two fish vets at either the VM2 or VM3 level (experience and qualification dependent). There are two pending vacancies both based on Vancouver Island: one veterinary position is available in the Fish Health division of Aquaculture Management Division (AMD) based in Courtenay, British Columbia, the second veterinary position is with the Salmon Enhancement Program (SEP) based in Nanaimo, BC, but other work locations may be considered. Both positions will be offered initially as a six month term, with the option for indefinite employment for suitable candidates.

Salary will range from \$87,794 to \$112,609 (Canadian) depending on candidate experience and qualifications. Suitable candidates will need a DVM or equivalent, and be eligible for membership in a Canadian veterinary association. Job duties are varied but candidates must be willing to work overtime and be physically capable and willing to ride in boats, planes and vehicles for long durations, and perform field work in inclement weather. Previous experience with production animal medicine is a requirement, and preference will be given to candidates with fish, enhancement and/or aquaculture experience.

AMD has a mandate to oversee and regulate aquaculture activities within BC, with a program emphasis on salmon farming. More information about AMD's fish health program can be found at: <http://www.dfo-mpo.gc.ca/aquaculture/protect-protege/fish-health-sante-poissons-eng.html>

The Salmonid Enhancement Program (SEP) plays a key role in DFO's work to conserve and manage Pacific salmon stocks. This is accomplished through a number of activities, including freshwater hatcheries. More information about SEP can be found at: <https://www.pac.dfo-mpo.gc.ca/sep-pmvs/index-eng.html>

A formal federal competition is pending and will be posted on the GC Jobs page in January: <https://www.canada.ca/en/services/jobs/opportunities/government.html>.

Facility Team Member

The Center for Aquaculture Technologies

Victoria, PEI

Link: <https://aquatechcenter.com/career/feedtech-center-manager/>

The Center for Aquaculture Technologies Canada, a private aquaculture innovation and research company has openings for suitably skilled staff to support the Victoria (PEI) facility and its ongoing operations. Facility Team Members are sought with the following skillsets, candidates that have overlapping competencies would be considered positively.

Job Duties and Responsibilities:

- Assist in the daily operations of the aquarium facilities in compliance with regulatory and quality guidelines.
- Performs daily monitoring and data collection related to aquaculture and facility functions.
- Performs daily and routine maintenance and monitoring of equipment such as HVAC, plumbing, electrical, and water systems
- Assists in setting up and decommissioning of aquaculture systems.
- Helps to maintain the efficiency of operations, adheres to standard operating procedure, and the preventive maintenance program.
- Must be available to be part of the scheduled rotation for weekend work and after-hours on-call monitoring of the facility.
- Competence to perform fish husbandry tasks and to monitor and maintain fish stocks (Training will be provided).

Experience/Requirements:

- A minimum of a high school diploma.
- Experience in the production of aquatic species and in the operation of aquaculture systems.
- 4th class power engineer ticket will be considered an asset.
- Mechanical aptitude and skills
- Must be eligible to work in Canada.
- Physically able to handle tasks that could include lifting, bending, and climbing, wearing PPE, exposure to wet and cold environments, and hot environments.
- Ability to work as part of a team in compliance with facility standard operating procedures.
- Prior experience in a CFIA regulated/GLP environment will be considered assets.
- Willingness to learn new skills and to perform routine tasks.
- Demonstrable organizational skills with the ability to multi-task.
- Self-motivated with a demonstrated ability to think creatively and solve problems.
- Fosters a positive work environment congruent with the company values and philosophy.

Key Qualifications:

- Commitment to CAT's Core Purpose: Dedication to and passion for CAT's core purpose: We are driven by the transformative potential of aquaculture. To feed the world, support the environment, and sustain the planet. Our purpose is to unlock this potential.

CATC offers a competitive salary and benefits including group health care and retirement savings plans.

Quality Assurance Specialist
AquaBounty Technologies, Inc.
Fortune Bridge, Prince Edward Island

Link: [website](#)

AquaBounty Technologies, Inc. has an opening for a QUALITY ASSURANCE ASSOCIATE working at our Prince Edward Island farm. This position reports to our Director-Regulatory Compliance and is responsible for providing oversight, leadership and guidance to the operations and research staff to help ensure adherence to the company's regulatory compliance requirements. AquaBounty's operations and processes are conducted in accordance with cGMP regulations. Quality assurance oversight and audits will be provided for regulated research, validation, facilities, processes and electronic systems.

Requirements:

- Bachelor of Science degree in Biology, Biochemistry, Chemistry or a comparable combination of education and experience in a related field. Knowledge and understanding of molecular laboratory procedures are key assets.
- 3+ years leadership experience working in a cGMP or GLP regulated environment.

Additional skills:

- AquaBounty is an aquaculture company. Knowledge and experience working in a Seafood HACCP or RAS aquaculture system is preferred.
- Excellent interpersonal skills to allow for collaboration within AquaBounty teams helps foster a culture of compliance.
- Detail-oriented.
- Scientific writing experience.
- Ability to work efficiently in the Microsoft suite of business products, including MS Word and MS Excel

Responsibilities:

- Provide leadership and guidance to operations and research staff for the continued adherence to the compliance activities at the company's sites.
- Manage and conduct periodic compliance audits of facilities, processes and containment, support compliance activities.
- Manage and maintain quality system for document control including but not limited to the issuance, review, revision, and distribution of the SOPs at the facility in PEI, and at the company's other facilities, as needed.
- Manage AquaBounty's system of electronic signatures. Provide support and advice, as needed, in the validation of regulatory processes and computer systems.
- Provide training in regulatory compliance subject matter. Participate in regulatory inspections.

AquaBounty is a leader in aquaculture, using new technology in new ways to deliver game changing solutions to global problems. We feed the world and strengthen our communities while caring for our people, our environment, and our fish.

We offer a competitive health and welfare benefit package, 13 paid holidays, paid vacation and sick leave.

Assistant Professor of Aquaculture

Lake Superior State University

Sault Ste. Marie, MI

Open until filled

Link: <https://jobs.lssu.edu/postings/2781>

Lake Superior State University (LSSU) seeks qualified applicants for a tenure track faculty position in Aquaculture starting in August 2021, with a dual appointment within LSSU's new Center for Freshwater Research and Education (CFRE; www.lssu.edu/cfre) and the School of Natural Resources & Environment (<https://www.lssu.edu/snre/>).

This is a 12 month position with administrative (50%), research (25%) and teaching (25%, minimum of 3 contract hours per semester) responsibilities during the 9 month academic year, and administrative (50%) and research (50%) responsibilities during the remaining 3 months. Administrative responsibilities include, but are not limited to, providing vision for and oversight of CFRE Fish Hatchery operations, developing and managing the hatchery operational budget, supervising hatchery personnel, and working with internal and external partners to ensure smooth operation of the hatchery. Research responsibilities include creating an active, externally-funded research program in aquaculture that engages undergraduate students and external collaborators, publishing research results in peer-reviewed scientific journals, presenting at professional conferences, acquiring external funding for research, and maintaining and developing collaborative relationships with state, federal, and tribal agencies. Teaching responsibilities include teaching Freshwater Fish Culture, Internship in Aquaculture, Apprenticeship in Fish Culture, and contributing to our undergraduate research seminar series. Additionally, the successful candidate will be expected to develop an academic program in aquaculture (AS or BS level) and any required course(s). Academic advising and mentoring undergraduates engaged in research are also expected.

LSSU is a small (<2,000 undergraduate students) state university located in the beautiful Upper Peninsula of Michigan. The campus sits on the St. Marys River, the sole outflow of Lake Superior and international boundary with Canada, and provides numerous educational and professional opportunities in aquaculture, fisheries management, and aquatic ecology. Additionally, LSSU is surrounded by three Great Lakes and many state, provincial, and national forests and parks that provide tremendous recreational opportunities and a high quality of life.

The CFRE Fish Hatchery (<https://www.lssu.edu/cfre/hatchery/>) houses a student-run Atlantic salmon hatchery, providing hands-on classroom opportunities, and the new Barch CFRE building is expected to be constructed and open in 2021. The Barch CFRE will provide expanded research facilities, including an analytical lab and experimental mesocosms, along with a Great Lakes visitors center and discovery center for K-12 education, all along the shores of the St. Marys River. The new facility will be uniquely positioned to build partnerships to advance Great Lakes education, research, and community engagement in the region. This new position will play a key role in contributing to the growth of the CFRE and related undergraduate opportunities.

The SNRE provides exceptional lab space, specimens, and equipment for education and research. Success of SNRE students stems from extensive interaction with faculty during hands-on labs, student research, and active student organizations. Most students within SNRE are required to complete senior thesis research and they are encouraged to present their research at regional and national scientific conferences. Faculty also work closely in advising student clubs, including the nationally recognized Fisheries and Wildlife Club (student sub-unit of the American Fisheries Society). The successful candidate would be expected to contribute to university service, including advising student organizations.

Minimum Qualifications

Doctoral degree in Aquaculture closely related discipline appropriate to the assignment is required at the time of appointment. The successful applicant should have administrative experience, demonstrated excellence in research, and teaching experience.

Desired Qualifications

Familiarity with aquaculture of salmonids, experience including undergraduates in research, and providing professional opportunities for students outside of class.

Preferred Qualifications

Be able to accompany students on field labs, actively lead and participate in field activities in, on and off the water; be able to lift up to 25 pounds; possess a valid driver's license and operate a 4WD truck and motor boat.

Aquaculture Veterinarian

Newfoundland Dept. of Fisheries and Aquaculture

St. Alban's, NL

Open until filled

Link: www.hiring.gov.nl.ca

See attached pdf.

Zebrafish Related Job Announcements

<https://wiki.zfin.org/display/jobs/Zebrafish-Related+Job+Announcements>

RESOURCES/NEWS

Aquatic Animal Drug Approval Partnership (AADAP) Updates are now available online:

https://www.fws.gov/fisheries/AADAP/aadap_update.html

VERMONT FISH & WILDLIFE News Release

For Immediate Release: December 17, 2020

News Contact: Adam Miller, Adam.Miller@vermont.gov, 802-777-2852

Vermont Fish and Wildlife Department Fish Health Laboratory Renamed in Honor of Fish Health Biologist Dr. Cassidy Hahn Shaw

On Thursday, December 17th, 2020, friends, family and past work colleagues from the Vermont Fish and Wildlife Department (VTFWD), the State of Vermont, the United States Geological Survey (USGS), as well as the United States Department of Agriculture (USDA), gathered virtually to acknowledge the career accomplishments and contributions of Dr. Cassidy Hahn Shaw with the dedication and renaming of the VTFWD's new fish health laboratory; the Dr. Cassidy Hahn Shaw Fish Health Laboratory.

Dr. Shaw was a previous fisheries biologist and research assistant for the USGS Leetown Science Center, a past research microbiologist with the USDA National Center for Cool and Coldwater Aquaculture Research, a past VTFWD fish health biologist, and most recently the VTFWD's fish culture operations manager. Prior to her resignation from VTFWD due to health reasons, Dr. Shaw was instrumental in the final completion and installation of the new fish health laboratory. Throughout Dr. Shaw's career she worked on significant fisheries projects and research such as analyzing genetic resistance to bacterial coldwater disease in cultured rainbow trout, diagnostics and molecular analysis of melanistic tumors on brown bullhead in Lake Memphremagog,

the discovery of a novel aquareovirus in landlocked Atlantic salmon in Lake Champlain, as well as many other fish culture and fish health projects. Her work ethic, perseverance, managerial excellence, and willingness to tackle new, complex challenges led to the renaming and dedication of the fish health laboratory in her name.

A zoom meeting recording of the ceremony is included below.

Zoom Meeting Recording Link:

https://us02web.zoom.us/rec/share/rDQRBKiQ0fjt1tsGDxaZ3mNGLQ34W70FX699m09kSOyF4mDz37Ypc5w8VhiQQxwO.rIS3bCu51sXhw4_t

Zoom Meeting Recording Passcode: JR1%^qqZ

Dr. Shaw currently resides in Jefferson, Maryland with her husband and two children. Her dedication to her family, her work, and her colleagues are to be noted and the impact that she has on people, both professionally and personally is extraordinary.

With Dr. Shaw, her friends, family, and work colleagues present on the Zoom meeting, a plaque was revealed that is now displayed at the entrance to the renamed lab that reads (pics below):

Dr. Cassidy Hahn Shaw Fish Health Laboratory

A past employee of the Vermont Fish and Wildlife Department, The United State Department of Agriculture, and the United States Geological Survey, Dr. Cassidy Hahn Shaw's commitment and career accomplishments in the fields of fish health, fisheries, and fish culture cannon be overstated.

Her contributions to the field of fisheries and science in general, both in the State of Vermont and beyond, are to be remembered for years to come.

This fish health laboratory, dedicated in her name, recognizes her perseverance, strength, and commitment to scientific and managerial excellence that echo through the years to promote sound scientific management of Vermont's fish and wildlife resources for future generations.



NEW FEATURE – EDITOR’S RANDOM PICS



Paramyxovirus sp. CPE on CHSE-214 cells, 25x, second passage at day 19, from spring Chinook broodstock, Round Butte Hatchery, Madras, OR, October 2020.

We're Hiring.

Aquaculture Veterinarian Permanent - St. Alban's, NL Department of Fisheries and Aquaculture

Are you...

- looking to build a successful career of clinical field work, frontline medicine and applied research fieldwork in finfish, shellfish and biosecurity?
- wanting to work within the newest state of the art aquatic diagnostic facility in the country with on site tech support?
- looking to grow our province's fledgling industry into a world renowned and respected operation?
- interested in supporting activities in fish husbandry, vaccination, disease control and nutrition?
- looking to build on your Doctor of Veterinary Medicine with our commitment to provide you with a fully supported continuing education environment?
- someone who enjoys travel, autonomy and the outdoors?

We are...

- located on the historic Connaigre Peninsula and completing construction of our new Diagnostic Laboratory and Regional Office in the summer of 2011.
- able to support you in adding to the current aquaculture health knowledge.
- able to support you in adding to current knowledge with the presentation of your findings to the worldwide scientific community.
- offering a work environment that will support your clinical field work and applied research through our state of the art facility.
- offering a work environment that promotes and supports your continued learning.

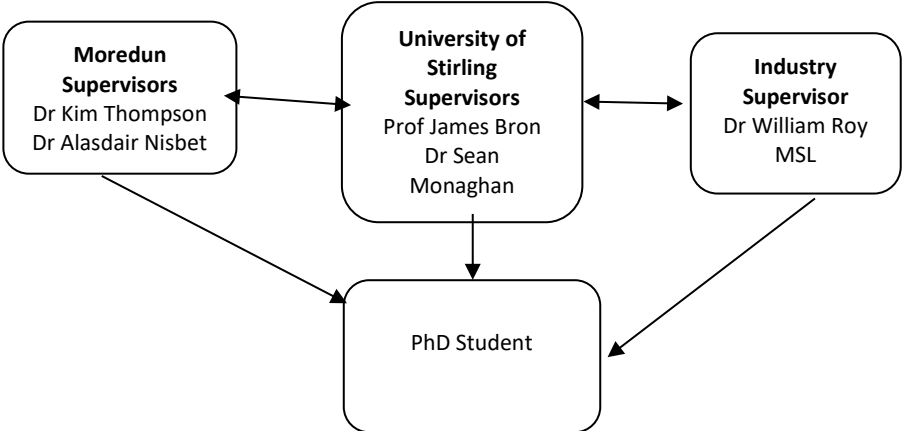
Upon offer of employment, the successful candidate is required to be licensed to practice veterinary medicine in the province. For additional information on this position, please contact Dr. Daryl Whelan at (709) 729-6872.

The public service is an equal opportunity employer and values diversity in its workforce. Please forward your resume, quoting competition number FA.10.11.389. Salary: \$74,929.40 - \$88,561.20. Please apply online or send resume via mail to: Recruitment Centre, Public Service Commission, 50, Mundy Pond Road, P.O. Box 8700, St. John's, NL , A1B 4J6 or Fax: 709-729-6737. Closing Date: Open Until Filled.



www.hiring.gov.nl.ca

PhD STUDENTSHIP DESCRIPTION

Studentship title:	Advancing control of sea lice (<i>Lepeophtheirus salmonis</i>) through development of sea louse <i>in vitro</i> assay systems.
Stipend	UKRI-level stipend
Department:	Vaccines and Diagnostics
Supervision:	 <pre> graph TD MS["Moredun Supervisors Dr Kim Thompson Dr Alasdair Nisbet"] <--> US["University of Stirling Supervisors Prof James Bron Dr Sean Monaghan"] US <--> IS["Industry Supervisor Dr William Roy MSL"] MS --> PS["PhD Student"] US --> PS IS --> PS </pre>
Staff reporting to post holder:	None
Main purpose of studentship:	The aim of this studentship is to develop <i>in vitro</i> culture/feeding assay systems that will serve both to reduce the number of fish used in sea lice research and provide novel <i>in vitro</i> research and bioassay approaches.

Main duties of post holder:

- (1) To establish artificial grazing substrates [(e.g. agar containing attractants and nutrients (e.g. fish blood, cells, mucus)] to allow the completion of the sea louse life cycle *in vitro* and to serve as a platform for delivering treatments orally to the sea lice.
- (2) To establish continuous sea louse cell lines for studying different aspects of sea louse biology.
- (3) To examine the feasibility of adapting tick explant culture approaches for sea lice, for use in sea lice research.
- (4) To develop bioassays using whole sea lice at different life stages, maintained *in vitro*, as an indirect method for screening vaccine candidates and other immunotherapies

PERSON SPECIFICATION

	Essential	Desirable
Attainments:	Candidates should have (or expect to achieve) a minimum of a 2:1 Honours degree in a relevant subject.	Understanding of one or more relevant subject areas such as: immunology, cell biology, parasitology, or veterinary sciences.
Experience:	Experience of working within a laboratory.	A background in Aquaculture.
		Experience in cell culture or bio-imaging.
	Knowledge in using basic IT packages (word processing; spreadsheets; internet browsers; e-mail).	
Skills:	Communication - excellent interpersonal and communication skills when dealing with a wide range of managers and staff	
	Managing relationships – ability to deal with a wide range of people with tact and diplomacy Able to build and maintain effective working relationships with a range of people.	
	Team working - ability to work flexibly and effectively as part of the team.	
	Resilience - strong ability to work with ambiguity and constantly changing set of circumstances and issues.	

	Essential	Desirable
Skills:	Planning and organisation - able to prioritise and plan activities taking into account deadlines and resources.	
	Decision making – able to take independent action where necessary in line with policies and procedures	Ability to quickly assimilate complex information and take effective decisions when required
	Flexibility – ability to adapt and work effectively with a variety of situations, individuals or groups. Able to understand and appreciate different and opposing perspectives on an issue and to adapt an approach as the situation changes	
Other skills (please specify)		
Other requirements (please specify)		

**GFI #61—Special Considerations, Incentives, and Programs to Support the Approval
of New Animal Drugs for Minor Uses and for Minor Species Guidance for Industry
Draft Guidance (July 2020)**

*Comments prepared by Jesse Trushenski, reviewed by the AFS FHS Policy/Position Development Committee (PPDC),
and provided to the AFS FHS membership as “food for thought” as this draft guidance document is reviewed.
Please note that these comments should not be interpreted as official opinions, positions, or policies of the AFS-FHS
at large.*

RE: Docket number FDA-1997-D-0444, Draft Guidance for Industry (GFI) #61, Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species

To whom it may concern:

Thank you for the opportunity to comment on Draft GFI #61. **INSERT ORGANIZATION HERE** respectfully requests that the Food and Drug Administration (FDA) consider the following issues we have identified in the draft guidance. **INSERT ORGANIZATION’S BONA FIDES HERE**. The **ORGANIZATION** unequivocally supports efforts to increase the availability of safe and effective drug products for minor species. However, we have identified a number of ways in which the draft guidance is inaccurate, inconsistent, or unlikely to advance such efforts. Our comments related to draft GFI #61 follow:

General: Executive Order on Promoting American Seafood Competitiveness and Economic Growth (issued 5-7-20) orders the federal government to, “...identify and remove unnecessary regulatory barriers restricting American fishermen and aquaculture producers...” However, the draft guidance has been revised in a number of ways that will increase data requirements and the cost associated with drug approvals in minor species, effectively *increasing* barriers to the sustainable development of aquaculture. These changes are not supported by evidence suggesting that existing guidance or practices was insufficient to address public safety or concerns related to human health, target animal safety, environmental safety, or product effectiveness.

IV. A. Jurisdiction: As noted in this section, the Environmental Protection Agency (EPA) is responsible for regulation of pesticides. However, FDA has assumed authority to regulate a number of external sanitizing agents or disinfectants which are not intended to affect the structure or function of the target animals, but to reduce pathogen loads in the external environment (e.g., hydrogen peroxide,

chloramine-T). These products do not meet the definition of an animal drug¹, but rather that of a pesticide², and the use patterns are analogous to that of EPA-regulated fogging disinfectants commonly used by the poultry industry. The draft guidance does not attempt to differentiate between products that should be considered animal drugs and those that should be considered pesticides. In the absence of clear guidance to this effect, we are concerned that FDA will assume regulatory authority of all fish health management products (excluding biologics, like vaccines), regardless of whether these products meet the definition of an animal drug. We recommend this section be expanded to clearly define external sanitizing agents or disinfectants as pesticides subject to EPA (not FDA) regulatory oversight.

XI. C.8. Aquaculture Species Grouping: The original language in GFI #61 indicated that “Demonstration of effectiveness in one species from any of four broad groupings (cold freshwater, warm freshwater, cold salt water, warm salt water) could be considered sufficient evidence of effectiveness against the same pathogens in all other species within that particular group. The applicant should present a sufficient scientific justification for such extrapolation. Furthermore, with such a scientific justification, demonstration of effectiveness in one species from each group could be considered sufficient evidence of effectiveness against the same pathogen in all fish (if such a pathogen occurs in such a broad spectrum of environments).” Although the draft guidance does not explicitly preclude such an approach, it sets forth a standard to require a substantially greater amount of data involving more species. In practice, FDA has not adhered to its previous guidance, typically requiring data demonstrating safety and effectiveness in six representative species (two each in coldwater, coolwater, and warmwater groupings) for “all freshwater-reared finfish” indications. The draft guidance serves to normalize FDA’s practices that were inconsistent with the previously issued guidance and more onerous with respect to data requirements.

The inclusion of suckers and sturgeons—but not other cultured species—in the Guidance could be interpreted to indicate that FDA considers these species to be model organisms or ‘representative’ Coolwater species. Suckers and sturgeons represent an exceedingly narrow segment of fish cultivation in the USA and represent species that are phylogenetically divergent from the other species listed. Sturgeons, in particular, exhibit distinctly different life histories and should be considered an exception rather than the rule for Coolwater fish biology. Listing these species as ‘representative’ is inconsistent with the known biology of these organisms and the purpose of identifying recommended species for the purpose of drug approval work. We do not believe the suggestion—intentional or otherwise—that suckers and sturgeons are ‘representative’ Coolwater species is well-justified and recommend they be deleted from the lists of species provided in the draft guidance.

¹The term “drug” means articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles other than food intended to affect the structure or any function of the body of man or other animals (<https://www.fda.gov/animal-veterinary/resources-you/fda-regulation-animal-drugs>).

² Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines a “pesticide” as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” (<https://www.epa.gov/pesticide-registration/determining-if-cleaning-product-pesticide-under-fifra>)

The inclusion of tropical ornamental finfish on a list that could be interpreted as ‘representative’ Warmwater species is similarly problematic. In addition to the extraordinarily wide range of taxonomy and associated life histories that could be considered part of this artificial grouping (many of which would be considered atypical relative to the most commonly cultivated fish in the USA), these species are not considered food fish as indicated elsewhere in the draft guidance. Moreover, inclusion of tropical ornamental finfish in this section of the draft guidance pertaining primarily to food fish creates confusion regarding FDA’s consideration of ornamental fish as being distinct from food fish (i.e., in the context of Index drug products). Again, the perception that tropical ornamental finfish are ‘representative’ is inconsistent with the biology and uses of these organisms and the purpose of identifying ‘representative’ species for drug approval work.

The statement, “Although these groups are based on temperature, they are akin to species groups based on family,” is not clear. The wide range of taxonomic families listed for the Coolwater and Warmwater groupings is evidence that each temperature groups contains representatives from several families. It is encouraging that FDA appears to consider various means of grouping/categorizing fish for drug approvals, but the draft guidance should not indicate temperature and taxonomic groupings as being equivalent—they are not. Further, the inclusion of hybrid striped bass as a representative warmwater species is not well-justified, as the optimal temperature for growth in this species is ~25°C. The temperature range (>26°C) is provided for Warmwater species, but not for Coldwater or Coolwater species.

The statements, “CVM also has considered salmonid finfish and non-salmonid finfish groups in freshwater,” is the most biologically sound and practical of the recommendations provided. We recommend striking the text pertaining to the temperature groupings and retaining only this recommendation and the text describing the possibility of pursuing other species groupings as can be justified.

The statements regarding the possibility of species groupings for saltwater species are vague and inconsistent with experience to-date. FDA has generally directed those pursuing saltwater finfish approvals (e.g., for AQUI-S 20E) to follow the same six representative species paradigm used for freshwater finfish approvals. Guidance should be developed to identify ‘representative’ saltwater species and to indicate that, if a drug product is proven safe/effective (i.e., data are accepted in support of Target Animal Safety and Effectiveness Technical Sections) in at least one ‘representative’ freshwater and one ‘representative’ saltwater fish, additional data from other species will generally not be required. We urge FDA to refer to data collected via the National INAD Program (U.S. Fish and Wildlife Service Aquatic Animal Drug Approval Partnership Program) and via FDA’s own post-approval reporting mechanisms for evidence to justify parallel processes with equivalent data requirements for freshwater and saltwater finfish approvals.

The statement, “Drug absorption may be different in saltwater fish...compared to a freshwater fish...” appears to refer to water-based treatments. The physiological, internal ‘environment’ does not vary appreciably between representative freshwater or saltwater finfish species. To our knowledge, there is no evidence suggesting that the metabolism of orally delivered or injectable drug products differs in

freshwater vs. saltwater species. The text should be modified to indicate these statements refer to water-borne treatments which may be affected by differences in water chemistry.

XI. C.10. Water Quality for Studies in Aquatic Species: The suggestion that additional tests for “heavy metals (including copper), chlorine, ozone oxidation reduction potential, etc.” may be important for “understanding the overall health of the aquaculture system” is unclear and does not appear warranted in most circumstances. It is unclear what is meant by “overall health” or under what circumstances the use of a drug product might contribute to a change in heavy metal concentrations or chlorine levels (unless the drug itself were a metal or chlorine-based product) in the rearing system. Demonstrating adequate water quality for the target species is an important element of conducting valid research with aquatic organisms, but this suggestion does not appear biologically warranted or generally applicable. FDA is able to require the collection of additional data as part of any study protocol submitted for concurrence. This is the correct mechanism for addressing the unique circumstances where additional water quality parameters are relevant and data collection is required, not in guidance meant to apply generally to all or most circumstances. Inclusion of this statement does not appear to reflect a legitimate need for relevant data, but rather the FDA practice of continually ‘raising the bar’ with respect to data requirements.

XII. B. 2. Pharmacokinetics for Aquatic Species: To our knowledge, use of pharmacokinetic (PK) data has not resulted in the modification of data requirements for any of the currently approved aquaculture drugs or drugs currently in the drug approval ‘pipeline’. If PK data and the “Phish-Pharm” database are to be used effectively, FDA should develop guidance describing generally accepted extrapolations between species based on this information.

XII. B. 2. Pharmacokinetics for Aquatic Species: As noted above, this section serves to normalize FDA’s practice of requiring substantially more data than the previously issued guidance describes as necessary for “all finfish” or “all freshwater-reared finfish” indications. We recommend that this text be modified to reflect our comments above and the previously issued guidance.

XII. B. 3. Effectiveness for Aquatic Species Groups

The statement, “Using this approach...the two studies in each fish species grouping should be conducted by two different investigators at two different locations using two different fish species,” is unnecessarily restrictive, particularly given the limited number of aquaculture laboratories capable of and interested in conducting work according to FDA-concurred research protocols. It is unclear whether multiple investigators/locations are required for drug approval work in major species. Regardless, this new addition to the draft guidance is an unnecessary, unwarranted impediment to conducting research in support of drug approvals for finfish.

Peer-reviewed literature and other data not generated in the context of an FDA-concurred protocol have generally not been considered sufficiently compelling to fully or partly address data requirements for aquatic species. Various reasons for this have been given in the past, including the lack of access to raw data, intellectual property issues/permissions, etc. Clear guidance is needed to identify what

elements are necessary for peer-reviewed literature or other resources to be considered legitimate/usable.

A major hurdle for the collection of effectiveness data is the requirement that effectiveness studies be conducted in the context of 'naturally occurring outbreaks', i.e., data from controlled disease challenges have not been considered adequate for demonstrating effectiveness in aquatic species. We recommend the inclusion of language to allow/encourage such studies to be used to satisfy the Effectiveness Technical Section.

The recommendations regarding a "risk-based approach to a "freshwater-reared in finfish" indication..." is well-considered. However, these recommendations are inconsistent with current FDA practice and other elements of the draft guidance regarding the need to conduct studies in six representative species for an "all freshwater-reared finfish" indication. Also, this section does not address the situation where an indication involves a dose range (e.g., 10-50 mg/L) to address species or environmental-based differences in effective treatment.

XII. C. 1. a. Antimicrobial Drug Indications for Minor Species: Regarding identification of pathogens as contributing to the disease outbreak in the study, we recommend inclusion of language acknowledging that some disease are caused by a collection of pathogens (e.g., systemic flavobacteriosis, bacterial gill disease) and many aquatic pathogens are not readily identified beyond the level of Genus (e.g., *Gyrodactylus* and *Dactylogyrus* spp.). The pathogen grouping issue is addressed in section XII. C. 1. b. with respect to parasites, but this concept should be expanded to include all aquatic pathogens.

The recommendation to collect isolates from a range of culture sites is of uncertain value (efforts to characterize *Gyrodactylus* spp. and their susceptibility to hydrogen peroxide produced nothing of value with respect to drug development or approval efforts), but it would certainly add complexity and cost to existing efforts to develop antiparasitic drugs for aquaculture.

XIII. Reasonable Expectation of Effectiveness for Conditional Approval: We recommend inclusion of language to indicate that "experts" are not restricted to licensed veterinarians. Further we recommend that "experts" be defined by a list of required credentials or experience.

XIV. B. Special Considerations for Aquaculture Species Groups: One of the biggest limitations to the completion of Target Animal Safety studies is the requirement that these studies be conducted only in Good Laboratory Practice (GLP)-compliant facilities for aquatic species. There are only a few (perhaps less now?) aquaculture programs that are GLP compliant, which greatly restricts options for conducting these studies. There are other means to ensure high quality data are collected and we encourage the inclusion of language to this effect. For example, data collected to satisfy Effectiveness Technical Sections is considered adequate if conducted in compliance with Good Clinical Practices (GCP).

The draft guidance states, "Traditionally, one margin of safety study in each of the three temperature-based species groupings (coldwater, coolwater, and warmwater) has been sufficient to demonstrate safety in an indication for 'freshwater-rearing finfish'." However, the draft guidance also states, "...if the use pattern in the aquaculture industry suggests that there will be increased use in two species within a temperature grouping, CVM may request safety studies be conducted in both of those species." The

latter statement is not well-justified and does not appear to be supported by any evidence suggesting this practice would result in fewer adverse events. It is not clear how changes in use patterns are related to determinations of target animal safety—either the product is considered safe or not—and post-approval adverse event reporting mechanisms are already in place to capture unforeseen effects in untested species or circumstances. This appears to be another example of increasing data requirements without evidence to suggest that existing requirements/practices are inadequate.

The suggestion of proposing a reduced list of target tissues to be evaluated for immersion products is well-considered. However, in practice, FDA has generally not followed this recommendation. To our knowledge, FDA generally only allows for the reduction in the number of tissues to be evaluated for an immersion product after proving these tissues were not affected in two representative species. For example, satisfying the AQUIS 20 Target Animal Safety technical section for freshwater finfish required histological evaluation of gill, liver, and kidney tissues in two species (though not a third) despite the fact that internal tissues were almost certainly not going to be affected by short-term immersion in a eugenol-based sedative. This is an example of FDA guidance suggesting a relatively flexible approach, but one that is not upheld by those personnel responsible for making decisions related to data requirements/adequacy.

XV. D. 4. Edible Tissues: The statement, “The eggs of some finfish species are considered edible...”, seems to suggest that Human Food Safety studies will need to include gravid females of edible roe-producing species. Such studies would be of little-to-no informative value with respect to Human Food Safety, and they would be exorbitantly time- and resource-consuming. This is another example of ‘raising the bar’ without any justification to suggest that existing Human Food Safety requirements are inadequate. If there is a legitimate concern with respect to use of a drug product in roe-producing species it could be addressed via labeling (e.g., this product is not for use in fish from which edible roe is to be harvested).

Also, please see previous comments regarding the definition of external sanitizing agents/disinfectants as pesticides not animal drugs.

E. Special Considerations for Aquatic Species—Life Stage Considerations and Species Groups: The statement that, “Aquatic food-producing animals in their early life stages...are still considered to be food-producing animals,” appears to be inconsistent with the previously issued guidance as well as GFI #210 (Indexing), both of which recognize non-food life stages of food producing species. This statement is in direct conflict with Indexing.

The statement, “...some [fish eggs] are used as human food,” is not fully accurate. Only unfertilized ova are consumed as caviar or roe—fertilized eggs are not. There is no confusion regarding the classification of unfertilized vs. fertilized eggs—one is a tissue/gamete/possible food product, the other is an early life stage. The text must be revised to accurately reflect the distinctions between unfertilized and fertilized eggs.

XVI. Environmental Impact: In recent years, there has been a noticeable ‘mission creep’ with respect to the scope of the Environmental Safety team’s work. Whereas the guidance documents referenced in

Appendix 1 clearly limit the scope of the Environmental Safety evaluation to the effects of the drug product itself in the environment (e.g., direct discharge, animal excretions), in practice, the Environmental Safety team has expanded their charge to include evaluations related to the risk of the treated animals themselves existing in the environment. For example, they have considered the environmental risk associated with hybrid catfish in the environment when assessing the Environmental Safety of spawning aids used to produce hybrid catfish and the environmental risk of sterile fish in the environment when assessing the Environmental Safety of sterilizing agents. This is analogous to the Environmental Safety team considering the environmental risk of the practice of cattle grazing on public lands as part of their evaluation of the Environmental Safety of a new drug intended for cattle. Whether sterile or hybrid fish can be produced and released to the environment is the purview of state natural resource agencies and is well beyond the scope of the FDA to consider or enforce. We recommend the inclusion of language to generally limit the scope of the Environmental Safety evaluation.

XXI. B. The Index of Legally-Marketed Unapproved New Animal Drugs for Minor Species (the Index):

The MUMS Act is broader in its definition of what the Index is for, including “a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals”. This definition includes the possibility of Indexing drug products used to treat broodstock, not just early life stages. We recommend the text be modified to fully reflect the legislatively defined purpose of the Index.

On behalf of **ORGANIZATION**, thank you again for the opportunity to comment.