



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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July 16, 2018

Re: Animal Welfare Assurance
#A3423-01 (OLAW Case 2C)

Ms. Victoria G. Rivera
Interim Director for Research Compliance
Institutional Official for Animal Welfare Program
University of Hawaii-Manoa
2425 Campus Road, [REDACTED]
Honolulu, HI 96822

Dear Ms. Rivera,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 11, 2018 letter reporting an adverse event that affected research fish at the University of Hawaii, following up on an initial report on June 22, 2018. According to the information provided, OLAW understands that 750 Blue Tilapia juvenile fish died due to a failure of the aeration and water pump during the night. This occurred in a new fish facility which had not been inspected by the Institutional Animal Care and Use Committee (IACUC) and had not been confirmed to be operational. The IACUC determined that in addition to this incident, eleven fish had died upon arrival from the vendor, 125 fish died due to poor water quality, and that the remainder of the fish died when the pumps became clogged with algae. The IACUC also identified some expired fish feed and found that remote monitoring and notification for the pumps was not in place.

The corrective action consisted of the IACUC requiring installation of back-up automation and aeration pumps before stocking with fish. A replacement water pump and an inline water pump were installed, valves were re-engineered, drainage was improved, and a sump was added. The IACUC required the Principal Investigator (PI) to maintain daily observation logs which include water quality parameters; to label the tanks with protocol number, PI name, and contact information; to amend the protocol to include additional staff; to document all training; to update the standard operating procedures; to implement a vermin control program; to test the system without fish for at least two months; to store dead fish in a dedicated freezer; and to periodically test the backup systems. The PI was also directed initially test the program with a small amount of fish shipped, to obtain older fish, to test the water system with a few fish, to amend the protocol to include additional species, and to include all projected species used in the disaster plan. No fish will be allowed to be ordered until the system has been inspected by the IACUC and Fish Advisory Committee and remote monitoring notification devices are in place.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. If additional findings, either positive or negative, are made, please let us know so that they can be added to the case file for completeness. Thank you for keeping OLAW apprised on this matter.

Page 2 – Ms. Rivera
July 16, 2018
OLAW Case A3423-2C

Sincerely,

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For

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

(b) (6)



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11 July 2018

Dr. Axel Wolff
Deputy Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
RKL1, Suite 1050 (MSC 9782)
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Re: University of Hawai'i Animal Welfare Assurance #A3423-01
Adverse Incident Resulting in Fish Mortalities Follow-up; COMM-OLAW-2018-6-FU

Dear Dr. Wolff,

I am writing to OLAW to provide a follow-up report to the University of Hawai'i's (UH) initial report dated 22 June 2018; whereby, UH informed OLAW that an adverse incident occurred on 11 June which resulted in the death of an estimated 750 Blue Tilapia, *Oreochromis aureus* fry. The fish were estimated to be average of 1 inch in length and 0.8 grams each. The fish were air shipped in overnight oxygenated plastic bags from an east coast commercial fish vendor to the University of Hawai'i (UH) Maui College, Kahului campus on the Island of Maui.

Background

As you may recall from the initial report, the fish were shipped to the facility on 29 May 2018, and received on 30 May 2018. The fish were to be used for teaching and training by aquaponics trainees to qualified individuals with and without disabilities. The objective of the training was to prepare students for aquaponics technical career pathways by addressing technical training needs for qualified youth with disabilities to access higher education technical training and competency-based certification, and food safety Good Agricultural Practices (GAP).

The adverse incident was discussed by the IACUC during its 21 June 2018 business meeting. The fish facility at the Maui campus is new, and had not been IACUC inspected nor stocked fish before this incident. Upon notification of this incident, the IACUC insisted and required immediate installation of back-up automation and aeration pumps before obtaining replacement fish.

Since the incident had been reported, the Animal Welfare Program, Office of Research Compliance was informed that a new replacement nursery water pump was installed on 11 June 2018. In addition to the plans to mitigate aeration and water pump concerns with new apparatus and inspecting and correcting all air and water delivery systems, PVC, etc. for leakage and other concerns, a new nursery system inline water pump was installed on 19 June 2018.

Representatives of the University IACUC, comprised of the Fish Advisory Committee (FAC) aquatic species subject matter experts, scheduled an initial site assessment inspection and post-incident follow-up investigation for 5 July 2018.

IACUC/FAC Investigation

On Thursday, 5 July 2018, an IACUC subcommittee comprised of FAC members conducted person-to-person interviews at the UH Maui College Campus Greenhouse facility with personnel closely associated with this matter. The subcommittee met with the Principal Investigator (PI) who also is the Aquaculture Program Director, the Aquaculture Program Coordinator, the Director of the Maui campus Office

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of Continuing Education and Training (OCET), and an engineering student who assists in the management of the program's aquatic systems.

Although the protocol covering the fish activities was approved in 2017, the first shipment of fish fry was not received until 30 May 2018. Therefore, the system mechanics and concepts were not tested; thus, not confirmed to be operational.

During the interview, it was learned that eleven (11) fry mortalities occurred upon arrival. On June 05, 2018, approximately 125 fish died due to poor water quality resulting from mechanical issues with drainage, filtration, and overflows. During the night of June 10, 2018, the aeration and water pumps failed due to clogging with algae, resulting in the death of all remaining fish. The accumulation of incidences were reported to the IACUC on June 15, 2018.

To address apparent mechanical issues as a result of the incident, improvements have been made by replacing defective parts with re-engineered valves and drainage, adding a sump, and installing replacement aeration and water pumps.

IACUC/FAC Conclusion

There were no fish being housed at the Maui College Campus during the inspection. However, as a result of the inspection, the IACUC/FAC subcommittee identified the following noncompliant items, and identified other areas of program deficiencies that required attention before fish should be permitted to be housed at the Maui College campus facility and used in the IACUC approved protocol:

Minor Noncompliant Item (1)

- A bag of fish feed expired November 2016. Correction schedule - discard expired feed no later than 31 July 2018.

Significant Noncompliant Item (1)

- Remote monitoring and notification devices for electrical/pump failures listed in the Disaster and Emergency Preparedness Plan were not being implemented. Correction schedule - remote monitoring notification devices are required to be in place prior to replacing fish stocks.

Requirements to be Implemented Prior to Receiving New Fish: (8)

- Daily observation records are required when fish are housed. Daily pH, water temperatures, and weekly water quality testing (i.e., ammonia, nitrate, nitrite and dissolved oxygen) are required. All data must be documented.
- Label fish tanks with Protocol Number, PI name, and contact information.
- Amend the protocol to include additional core staff working with fish.
- Document all training of personnel, including volunteers and workshop participants.
- Update SOPs with currently used practices and procedures.
- Develop a vermin control program.

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A3423-2C



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Office of Research Compliance
Animal Welfare and Biosafety Programs

22 June 2018

Dr. Axel Wolff
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
RKL1, Suite 1050 (MSC 9782)
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Re: University of Hawaii Animal Welfare Assurance #A3423-01
Adverse Incident Resulting in Fish Mortalities; COMM-OLAW-2018-6

Dear Dr. Wolff,

I am writing to OLAW to report an adverse incident which resulted in the death of an estimated 750 Blue Tilapia, *Oreochromis aureus* fry. The fish were estimated to be average of 1 inch in length and 0.8 grams each. The fish were air shipped in overnight oxygenated plastic bags from an east coast commercial fish vendor to the University of Hawaii (UH) Maui College, Kahului campus on the Island of Maui.

The fish were shipped on 29 May 2018, and received on 30 May 2018. The fish were to be used for teaching and training of aquaponics trainees for qualified individuals with and without disabilities. The objective of the training was to prepare students for aquaponics technical career pathways by addressing technical training needs for qualified youth with disabilities to access higher education technical training and competency-based certification and food safety Good Agricultural Practices (GAP). Funding for the study originated from the University of Hawaii (UH) Community College (CC) Aquaponics Career and Technical Education and Training. PHS, VA, or NSF funding was not being used to support the activity.

Timeline and Response

On Wednesday, 13 June 2018, a Principal Investigator (PI) reported that on 11 June 2018, the adverse incident occurred. The PI identified mechanical failure of aeration and the water pump during an unattended night-time period leading to the death of the entire colony of fish fry in the self-contained quarantine tank.

IACUC

The adverse incident was discussed by the IACUC during its 21 June 2018 business meeting. The fish facility at the Maui campus is new, and had not been IACUC inspected nor stocked fish before this incident. The IACUC insisted and required immediate installation of back-up automation and aeration pumps before obtaining replacement fish.

Since the incident had been reported, the PI informed the Animal Welfare Program, Office of Research Compliance that a new replacement nursery water pump was installed on 11 June 2018. Furthermore, a new nursery system inline water pump was installed on 19 June 2018. The PI plans to mitigate aeration and water pump concerns with new apparatus and are inspecting and correcting all air and water delivery systems, PVC, etc. for leakage and other concerns.

Representatives of the University IACUC comprised of the Fish Advisory Committee aquatic species subject matter experts have confirmed and scheduled an initial site assessment inspection and post-incident follow-up investigation on 5 July 2018, and will report back to the full IACUC at the next business meeting on 19 July 2018.

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Please contact me at [REDACTED] (b) (6) or riveravg@hawaii.edu with any questions.

Sincerely,

[REDACTED] (b) (6)

Victoria G. Rivera, MPA
Interim Director, Office of Research Compliance
Institutional Official, Animal Welfare Program

c: Manuel G. Himenes, Jr., Chair, UH IACUC

[REDACTED] (b) (6)

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 26, 2018 11:07 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Hawaii Reports Adverse Incident Maui Campus

Thank you (b) (6) for this report. Dr. Wolff will respond soon.

Regards,
Joan

From: (b) (6) [mailto:(b) (6)@hawaii.edu]
Sent: Tuesday, June 26, 2018 12:51 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Victoria Rivera <riveravg@hawaii.edu>
Subject: University of Hawaii Reports Adverse Incident Maui Campus

Good Afternoon Dr. Wolff and OLAW Compliance Staff:

On behalf of Ms. Victoria Rivera, Interim Director for Research Compliance, Institutional Official for the UH Animal Welfare Program, please find the attached report.

Sincerely,

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