STAFF SUMMARY FOR APRIL 17, 2019

9. TRANSGENIC ZEBRAFISH (CONSENT)

Today's Item **Information** ☒ **Action** ☐

Receive an application for a permit to import, possess, transport or rear, or conduct research on, transgenic zebrafish.

Summary of Previous/Future Actions

- **Today's receipt of application** **Apr 17, 2019; Santa Monica**
- Review and consider action related to permit issuance Jun 12-13, 2019; Redding

Background

Pursuant to Section 671.1(a)(8)(H), Title 14, when DFW determines that a restricted species permit for transgenic aquatic animals should be issued, that decision must be reviewed by FGC. FGC may deny the issuance of a permit if it determines that the applicant is unable to meet the regulatory requirements for the importation, transportation, possession, and confinement of transgenic aquatic animals.

Additionally, pursuant to Fish and Game Code Section 15007(e), DFW must notify the California State Legislature's Joint Committee on Fisheries and Aquaculture and FGC upon receipt of a permit application for medical or scientific research conducted on transgenic finfish species. Notification must take place at least 30 days prior to the approval or disapproval of the permit.

This agenda item serves as notice to FGC that a restricted species permit application for use of transgenic zebrafish for research has been received from San Diego State University (Exhibit 1).

Significant Public Comments (N/A)

Recommendation

Receive the restricted species permit application and accept any public comment, under a motion to adopt the consent calendar.

Exhibits

1. DFW memo and permit renewal application, dated Apr 4, 2019

Motion/Direction

Moved by _____ and seconded by _____ that the Commission adopts the staff recommendations for items 4-11 on the consent calendar.

State of California
Department of Fish and Wildlife

Date: April 4, 2019

To: Melissa Miller-Henson
Acting Executive Director
Fish and Game Commission

From: Charlton H. Bonham
Director

Subject: **Agenda Item for the April 17, 2019 Meeting: Receipt of Restricted Species Permit Application to Possess Transgenic Zebrafish**

San Diego State University (SDSU) has applied for a Restricted Species Permit to possess transgenic zebrafish (*Danio rerio*). According to Title 14, Section 671.1(a)(8)(H), all approved applications to possess a transgenic aquatic animal shall be reviewed by the Commission at a regularly scheduled meeting. The Commission may deny the issuance of a permit if it determines that the applicant is unable to meet the regulatory requirements for the importation, transportation, possession, and confinement of transgenic aquatic animals.

The transgenic zebrafish will be used for biomedical research. Zebrafish have become a popular and commonly used organism for the study of vertebrate gene function and human genetic disease. The Department currently permits approximately 20 facilities to possess transgenic zebrafish for the purpose of biomedical research. SDSU has agreed to comply with containment and security conditions as specified in Title 14 of the California Code of Regulations. Fisheries Branch has coordinated with the regional staff responsible for this area and the Fish Health Lab. The Department recommends issuing SDSU a Restricted Species Permit to possess transgenic zebrafish.

If you have any questions or need additional information on this matter, please contact Kevin Shaffer, Chief, Fisheries Branch at (916) 327-8840.

Attachment

ec: Stafford Lehr, Deputy Director
Wildlife and Fisheries Division
Stafford.Lehr@wildlife.ca.gov

Kevin Shaffer, Chief
Fisheries Branch
Wildlife and Fisheries Division
Kevin.Shaffer@wildlife.ca.gov

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Senior Environmental Scientist
(Supervisor)
South Coast Region (Region 5)
John.O'Brien@Wildlife.ca.gov

California Natural Resources Agency
DEPARTMENT OF FISH AND WILDLIFE

RESTRICTED SPECIES PERMIT NO. 1726
2019 RESTRICTED SPECIES PERMIT RENEWAL APPLICATION
PERMITTEE TYPE:
PERMIT TYPE(S): RESEARCH - DETRIMENTAL SPECIES

CDFW Received DEC 17 2018 BY LRB

PERMITTEE'S BUSINESS NAME	CONTACT PERSON ~~RULON CLARK~~	CONTACT TITLE	BUSINESS PHONE/EXT.	EMAIL ADDRESS
SAN DIEGO STATE UNIVERSITY	Rick Gullzia	~~PROFESSOR, DEPT CHAIR~~ Director of Research Affairs	~~(619) 594-1837~~ 619-594-5938	rgullzia@sdsu.edu

MAILING ADDRESS	CITY	STATE	ZIP CODE	COUNTRY
~~DEPT OF BIOLOGY, 5500-6250~~	SAN DIEGO	CA	92182-1933	USA
CAMPANILE DR STREET ADDRESS (IF DIFFERENT THAN ABOVE)	CITY	STATE	ZIP CODE	COUNTRY

I HAVE CONTINUOUSLY RESIDED IN CALIFORNIA FOR THE LAST SIX MONTHS. YES [X] NO [ ]
Resident is defined as any person who has resided continuously in the State of California for six months or more immediately prior to the date of this application for a permit, any person on active military duty with the Armed Forces of the United States or auxiliary branch thereof, or any person enrolled in the Job Corps established pursuant to Section 2093 of Title 29 of the United States Code

PERMITTEE'S NAME (IF APPLYING AS AN INDIVIDUAL)	GO ID NUMBER	DATE OF BIRTH	DAYTIME PHONE
	~~GO02745705~~		

CHECK TYPE(S) OF PERMIT

ANIMAL CARE - DETRIMENTAL SPECIES	$506.50	
ANIMAL CARE - WELFARE SPECIES	$61.80	
AQUACULTURE	$506.50	
AZA - DETRIMENTAL SPECIES	$506.50	
BREEDING	$506.50	
FISH	$506.50	
NATIVE SPECIES EXHIBITING	$506.50	
[ ] NONRESIDENT BROKER/DEALER	$1,005.25	
[ ] NONRESIDENT EXHIBITING	$1,005.25	
[ ] NONRESIDENT NUISANCE BIRD ABATEMENT	$1,005.25	
[X] RESEARCH - DETRIMENTAL SPECIES	$506.50	506.50
[ ] RESIDENT BROKER/DEALER	$506.50	
[ ] RESIDENT EXHIBITING	$506.50	
[ ] RESIDENT NUISANCE BIRD ABATEMENT	$506.50	
SHELTER	$61.80	
[ ] SINGLE EVENT BREEDING FOR EXHIBITOR	$61.80	
PERMIT(S) FEE SUBTOTAL		$ 506.50

STANDARD INSPECTION FEE IS BASED ON THE NUMBER OF ENCLOSURES
CHECK NUMBER OF ENCLOSURES AND RECORD THE CORRESPONDING STANDARD INSPECTION FEE BELOW:

1-5 Enclosures	$248.49
6-25 Enclosures	$348.50
26-50 Enclosures	$566.75
51-100 Enclosures	$889.50
101-500+ Enclosures	$3,278.00

PERMIT(S) FEE SUBTOTAL		$ 506.50
NONREFUNDABLE APPLICATION FEE	$62.32	$ 62.32
STANDARD INSPECTION FEE		$ 248.49
AQUACULTURE INSPECTION FEE Applicants for aquaculture permits shall pay this inspection fee.	$1,645.50	$
ELE/MOU NEW FEE Applicants for research permits may pay the ELE/MOU fee in lieu of the standard inspection fee	$466.75	$
ELE/MOU RENEWAL FEE Applicants for ELE/MOU inspections shall pay renewal fee	$58.45	$
GRAND TOTAL		$ 817.31

WILL ANIMALS BE IMPORTED INTO CALIFORNIA? [X] YES, COMPLETE IMPORTATION SECTION [ ] NO, EXPLAIN

IMPORTATION ONLY - COMPLETE THIS PORTION OF THE APPLICATION IF YOU ARE IMPORTING ANIMALS INTO CALIFORNIA.

List Species to be Imported	No. of Animals	Origin (State or Country)
Transgenic Zebrafish (wt1b:CFP, vitdbp:GFP strains	100 embryos	North Carolina

Person/Business Shipping Animals	Day Phone
Dr. Weibin Zhou, PhD, Duke University	(919) 684-2907

Address	City	State	Zip Code
300 N. Duke Street, Suite 47-109 - DUMC 104775	Durham	NC	27701

Name of Carrier	Point of Entry into California
Not Yet Known	Not Yet Known

Applicant's Certification: *I certify under penalty of perjury under the laws and regulations of the State of California that all information on this application is true and correct and I am not violating any city or county laws. I agree to comply with the provisions of Section 671, Title 14, of the California Code of Regulations. I understand it is unlawful to use or possess a permit which was obtained by fraud or deceit (Fish and Game Code Section 1052b). I understand that in the event that this information is found to be untrue or incorrect, the permit will be considered invalid and must be surrendered where purchased and I will be subject to criminal prosecution. I further understand that failure to comply with the terms and conditions of a permit may result in revocation of current permit and/or denial of future permits. Violation of this section is a misdemeanor, punishable by a fine of not more than $1,000.00, imprisonment in the county jail for not more than six months, or both the fine and the imprisonment. In addition, I may be subject to civil penalties as stated in Fish and Game Code*

APPLICANT'S SIGNATURE (MUST BE IN INK) Date

X Rick Gullzia 12/07/18

FOR DEPARTMENT OF FISH AND WILDLIFE USE ONLY

REVIEWED BY/DATE TRANSACTION # ISSUED BY/DATE

California Natural Resources Agency
DEPARTMENT OF FISH AND WILDLIFE

RESTRICTED SPECIES PERMIT NO. 1726 Page 1

2019 INVENTORY OF ANIMALS RENEWAL

CDFW Received DEC 17 2018 BY LRB

ATTN: ~~RULON CLARK, PROFESSOR, DEPT CHAIR~~
Rick Gulizia, Director of Research Affairs
SAN DIEGO STATE UNIVERSITY
DEPT OF BIOLOGY, ~~5500~~ 5250 CAMPANILE DR
SAN DIEGO CA 92182-1933

LOCATION(S) OF ANIMALS NOTE: Animals being held at multiple locations require inspection certification by the Department that each of those facilities meet minimum applicable housing requirements as set forth in Sections 671.1(a)(8)(A-F), 671.2, 671.3 - 671.4, 671.4(g) and/or 671.7, Title 14, of the California Code of Regulations (CCR).

ADDRESS	CITY	STATE	ZIP	COUNTY
~~ANIMAL CARE/LIFE SCIENCE BLDG, ROOM 133~~	SAN DIEGO	CA	92182-4162	SAN DIEGO

Hardy Tower, Room 224

INSTRUCTIONS: Listed below are the animals you are currently authorized to possess. REVIEW AND EDIT: make any necessary changes (i.e. deaths, number of animal(s), age of animal(s), acquisitions, transfers, etc.) by crossing out and writing in changes, prior to submitting your renewal application. UNIQUE IDENTIFIERS AND METHOD (see Section 671.1(c)(3)(J), Title 14, of the CCR): Specify the number, letter or any combination thereof in the Unique ID field and use the following to denote identifying method in the ID Method field for required species: M=Microchip; T=Tattoo; or A=Alternative Method. The Department may approve an alternative method if the permittee provides written verification from a veterinarian accredited by the USDA explaining why it would be detrimental to the health of an animal to microchip or tattoo the animal and what alternative method of unique identification would be suitable. FACILITY IDENTIFICATION: Required for permittees whose permit conditions specify animal identification required other than those species specifically requiring animal identification. This identification may include but is not limited to the animals given name (i.e. Sally, Duke), intake ID, studbook ID, band number, or government or institution (i.e. AZA, USFWS) ID. AQUACULTURE AND FISH PERMITTEES: Identify the actual number in the No. field and identify either W=Weight; V=Volume; or C=Count in the Method field. IMPORTATION ONLY SECTION: Remember to complete this section of your renewal application for all animals being imported into California. ANIMAL CARE AND, NATIVE SPECIES EXHIBITING AND OTHER DESIGNATED PERMITTEES (see permit conditions): You are not authorized to obtain any new species or new animals without prior written approval from the Department.

UNIQUE ID	IDENTIFYING METHOD	COMMON NAME	SCIENTIFIC NAME	FACILITY ID	NO.	SEX	AGE YRS	AGE MOS	TBA*	NS**
A	Closed & isolated system, tank labels	Zebrafish, from the following transgenic strains: AB (wild type, not transgenic) Tg (ins:nfsb::mCherry) mitfa-/- Tg (VitDbp::GFp) Tg (wt1b::GFp)	Danio rerio	SDSU	1500	M/F	2			

I certify under penalty of perjury under the laws and regulations of the State of California that all information on this Restricted Species Permit Inventory of Animals form is true and correct. I understand that false or incomplete information may result in denial or revocation of a permit and/or criminal prosecution

APPLICANT'S SIGNATURE *(MUST BE IN INK)*	Date
X Rick Gulizia	12/7/18

State of California – The Natural Resources Agency -- EDMUND G. BROWN, Jr. Governor
DEPARTMENT OF FISH AND GAME CHARLTON H. BONHAM, Director
License and Revenue Branch
1740 North Market Boulevard
Sacramento, California 95834
(916) 928-5845
Fax (916) 419-7586
www.dfg.ca.gov

SAMPLE
EMERGENCY ACTION PLAN FOR
San Diego State University
Revised: November 9, 2018

a. List of the re-capture equipment available, including but not limited to darting equipment, nets, traps, and chemical immobilization drugs for animals listed on your inventory;

These fish species cannot survive in San Diego waters, and thus pose very low ecological risk. The waters along the California coast are also too cold to enable zebrafish breeding. All enclosures are contained in a larger rack system with circulating water, and therefore the risk of escape is near zero. In the rare event that a fish could escape its enclosure, it would be transported to the rack's internal water reservoir near the sump, and therefore is in secondary containment. In the case of emergency, such as a severe earthquake which is able to dislodge the secure rack system from the walls and building infrastructure, an escaped fish might possibly fall to the ground of the laboratory. This room is secured from public access, with only approved and secured individuals being permitted to enter and exit the room. The only exit from the room is a floor drain to the municipal wastewater system, on which a grate has been installed so that no fish could exit the room. Therefore, any fish falling to the floor would be out of the water and would perish. Therefore, there is VERY low risk of escape.

b. Description of humane lethal dispatch methods for various animals and a list of qualified personnel who are trained to carry out the methods;

If a fish escapes to the secondary containment chamber or the floor of the vivarium, all efforts will be made to return the fish to its proper tank using aquarium nets. However, if the fish has been out of water too long, it will be humanely euthanized to minimize discomfort and distress. Euthanasia is performed using MS-222 (tricaine) for 30+ minutes, followed by freezing in a carcass waste bag, and then disposal in biological waste containers. All laboratory personnel will be trained in these methodologies, and all protocols and personnel will be approved by the San Diego State University Institutional Animal Care and Use Committee.

c. List of medical supplies/first aid kits (both animal and human) and where they are located;

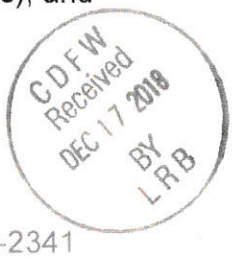
At any sign of distress or discomfort to fish, the animal will be humanely euthanized. Euthanasia is performed using MS-222 (tricaine) for 30+ minutes, followed by freezing in a carcass waste bag, and then disposal in biological waste containers. All laboratory personnel will be trained in these methodologies, and all protocols and personnel will be approved by the San Diego State University Institutional Animal Care and Use Committee.

First aid kits for laboratory personnel are located in room Hardy Tower 214, near other personal safety equipment such as an eye wash station and shower.

d. Description and number of mobile transport cages and equipment on hand to accommodate all animals listed on your inventory;

No adult fish will be allowed outside of room Hardy Tower 224 (vivarium), as they are only maintained as breeding populations on the automated system. Embryos for research will be collected into covered petri dishes, placed into a polypropylene secondary containment bin, and transported to the research laboratory, room Hardy Tower 204 (2 rooms down from the vivarium). Embryos are maintained inside of petri dishes, inside of a sealed incubator, and therefore pose no risk for escape.

e. List of emergency telephone numbers that includes 911, the local Department of Fish and Game regional office (find telephone number at www.wildlife.ca.gov/regions), and animal control agencies;



1 - 911
2 - CA Fish & Game Regional office
South Coast Regional Office: (858) 467-4201
3 - County/City Animal Control Agencies (insert here name/telephone number)
San Diego County Department of Animal Services, Emergency Line: (619) 236-2341
4 - Veterinarian - (insert here name/telephone number)
Mari Bray, mbray@lavcs.onmicrosoft.com, Phone: (858) 663-6107

f. Written plan of action for various emergencies (i.e. animal escape, animal evacuation, animal attack).

Zebrafish are not physically harmful to humans, and therefore pose to risk for attack or emergency. Because they cannot survive outside of tanks, any required evacuation can be controlled by placing tanks into polypropylene secondary containment bins and kept on a mobile cart. Zebrafish are unable to escape the facility due to various physical and physiological barriers, including drain covers, secure vivarium entrance, and the inability of the zebrafish to survive in ambient conditions (outside of water). Embryos are maintained inside of petri dishes, inside of a sealed incubator, and therefore pose no risk for escape.

Graduate and Research Affairs
Institutional Animal Care and Use Committee
San Diego State University
5500 Campanile Drive
San Diego CA 92182-8220
Tel: 619-594-0905

SAN DIEGO STATE UNIVERSITY

October 10, 2018

Professor Karilyn Sant
Public Health, San Diego State University

APF#: 18-09-011S
Title: *How Do Embryonic Exposures to Environmental Contaminants Alter Kidney and Embryonic Development?*
Protocol Category of Use: D
Subject: **IACUC Approval**

Dear Professor Sant:
The project referenced was reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) in accordance with the requirements pertaining to animal subjects protections within the Public Health Service Policy and USDA Animal Welfare Regulations on **October 10, 2018.** Approval carries with it the understanding that you will contact the Committee promptly to report any unanticipated or serious adverse events, to obtain authorization to implement any proposed changes to the protocol, to document a change in your affiliation with SDSU, and/or to report study completion. **Any proposed changes to the protocol must be submitted on an amendment form, reviewed and approved by the IACUC before those changes can be implemented. Submit addition or deletion of personnel to iacuc@sdsu.edu. Personnel added to the protocol must complete all training requirements prior to working with animals.**

Approval is only valid provided:

- **All personnel have completed the necessary training requirements;**
- **The necessary restricted species permit(s) have been obtained from California Department of Fish and Wildlife;**
- **The necessary approvals are in place from the SDSU Institutional Biosafety Committee for work with transgenic animals.**

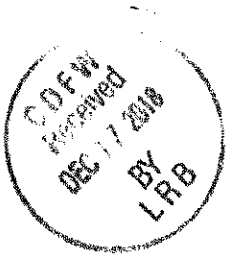
IMPORTANT: Your APF number is 18-09-011S. This number must be placed in all relevant places (i.e., fish tanks, husbandry log books, etc.) along with any other relevant information about the animal.

Protocol approval is valid for up to three years provided you submit annual continuation forms to the IACUC for review. Your 1st year annual continuation is due **October 10, 2019.** The IACUC office will send you a reminder to renew your protocol; however, **it is your responsibility to submit a completed Annual Continuation Form at least four weeks in advance of the due date.**

The IACUC office will send you the final version of your final approved protocol, it is your responsibility to maintain the current approved version of your protocol at all times for future reference and personnel training purposes. Any changes to this protocol must be reviewed and approved by the IACUC prior to initiation.

For questions related to this correspondence, please contact the IACUC office at (619) 594-0905 or e-mail iacuc@sdsu.edu.
Sincerely,

Todd W. Anderson, Ph.D.
Chair, Institutional Animal Care and Use Committee
TWA:clc
Protocol Expiration Date: October 10, 2021
Copy to: Institutional Biosafety Committee



Project Description, Kari Sant, SDSU

SDSU IACUC Animal Protocol Form #18-09-011S Approved October 10, 2018

The purpose of my research is to understand the risks associated with common drinking water contaminants during pregnancy, and how these gestational exposures may predispose children to diabetes. This study is important for characterizing human health risks associated with new and poorly understood hazards, such as perfluorinated compounds which have been detected in 99.7% of Americans. Perfluorinated compounds mostly act through a signaling pathway known as the Peroxisome proliferator-activated receptor (PPAR) signaling pathway, which has been widely implicated in kidney diseases. PPAR signaling has been explored as a pharmacological target for diseases such as diabetes and obesity, and therefore more information is needed to better understand how this affects human development. Ultimately, my goal is to help improve our understanding of the health consequences from these exposures, communicate these risks to stakeholders, and to inform technologies and policies which may reduce the associated health burdens. Zebrafish embryos are structurally and physiologically similar to human embryos during gestation, and can therefore be used in order to better understand human health risk.