## Staff Summary for December 11-12, 2024

# 3. Importation of Live Aquatic Plants and Animals for Research Purposes

Today's Item Information  $\square$  Action  $\boxtimes$ 

Consider adopting proposed amendments to regulations regarding the importation of live aquatic plants and animals for research purposes.

## **Summary of Previous/Future Actions**

• Notice hearing October 9-10, 2024

Today's adoption hearing
 December 11-12, 2024

# **Background**

At its October 2024 meeting, the Commission authorized publication of a notice of its intent to amend Section 236 related to importing aquatic plants and animals for research purposes. The notice was published in the California Regulatory Notice Register on October 25, 2024.

The goal of the recommended action is to add a provision to Section 236 to authorize registered aquaculturists to import live aquatic plants and animals into California for research purposes; the authorization would include shipments with detected diseases or pathogens, subject to specific conditions that maintain the existing disease control protections of Section 245, with limitations to prevent release, while providing for important research. The draft proposed changes to Section 236 would expand the permitting process and improve oversight of importing live aquatic plants and animals for research by:

- Adding "aquatic plants" to the existing exceptions in regulation (Exhibit 3) that currently only apply to live aquatic animals.
- Establishing that a registered aquaculturist, solely for research purposes, may import
  aquatic plants or animals for which a disease or pathogen has been detected in the
  shipment prior to importation, subject to written approval and permit conditions specified
  by the Department. The Department must be able to provide permit conditions that
  minimize risk of such importations for each permit.
- Requiring the registered aquaculturist to maintain all permitted aquatic plants or animals in a closed water system (as defined in subsection 671.7(a)(1)).
- Specifying that if a disease or pathogen listed in subsection 245(c) of the regulations
  (Exhibit 5), that was not detected prior to importation, is identified by a qualified fish
  pathologist, the registered aquaculturist must comply with existing regulations in Section
  245 and subsection 236(c)(5), which require the immediate destruction of the
  specimens or exporting them out of the state within an amount of time determined by
  the Department.

For a high-level summary of the rulemaking intent, see the Department memo in Exhibit 2. More details on the proposal, rationale for each draft proposed provision, and statutory background can be found in the initial statement of reasons (Exhibit 5).

# Significant Public Comments (N/A)

## Staff Summary for December 11-12, 2024

#### Recommendation

**Commission staff:** Adopt the proposed changes to regulations as recommended by the Department.

**Department:** Adopt the proposed amendments to regulations as described in the initial statement of reasons and identified in the proposed regulatory language.

#### **Exhibits**

- Staff summary for Agenda item 5 from October 10-11, 2024 Commission meeting related to importation if live aquatic plans for research purposes (for background purposes only)
- 2. Department memo, received September 27, 2024
- 3. Section 245, Title 14 (for background purposes only)
- 4. <u>Department email in-lieu of a pre-adoption statement of reasons, received November</u> 27, 2024
- 5. Initial statement of reasons
- 6. Proposed regulatory language
- 7. Economic and fiscal impact statement and addendum (STD. 399)

### **Motion**

Moved by	and seconded by	that the Commission adopts the
proposed	amendments to Section 236 related to	o importing aquatic plants and animals for
research p	ourposes.	

# Staff Summary for October 9-10, 2024 For Background Purposes Only

# 5. Importation of Live Aquatic Plants and Animals for Research Purposes

Today's Item Information  $\square$  Action  $\boxtimes$ 

Consider authorizing publication of notice of intent to amend regulations regarding the importation of live aquatic plants and animals for research purposes.

#### **Summary of Previous/Future Actions**

Notice hearing

October 9-10, 2024

Adoption hearing

December 11-12, 2024

### **Background**

Importation of most live aquatic plants and animals requires a permit under existing state law and regulations. Importation permits help minimize the risk of introducing harmful pathogens, parasites, and diseases to California's wildlife and ecosystems.

While existing regulations limit the scope of importation for research purposes, scientific research is essential to address the challenges posed by aquatic diseases or pathogens, and to identify solutions that can protect the condition of aquatic and other ecosystems. However, current regulations do not provide a mechanism to allow registered aquaculturists to import and conduct such research on aquatic plants and animals that are known to have a disease or pathogen prior to shipment.

The goal of the recommended action is to add a provision to Section 236 to authorize registered aquaculturists to import live aquatic plants and animals into California for research purposes; the authorization would include shipments with detected diseases or pathogens, subject to specific conditions that maintain the existing disease control protections of Section 245, with limitations to prevent release, while providing for important research. The draft proposed changes to Section 236 would expand the permitting process and improve oversight of importing live aquatic plants and animals for research by:

- Adding "aquatic plants" to the existing exceptions in regulation (Exhibit 3) that currently only apply to live aquatic animals.
- Establishing that a registered aquaculturist, solely for research purposes, may import
  aquatic plants or animals for which a disease or pathogen has been detected in the
  shipment prior to importation, subject to written approval and permit conditions specified
  by the Department. The Department must be able to provide permit conditions that
  minimize risk of such importations for each permit.
- Requiring the registered aquaculturist to maintain all permitted aquatic plants or animals in a closed water system (as defined in subsection 671.7(a)(1)).
- Specifying that if a disease or pathogen listed in subsection 245(c) of the regulations (Exhibit 5), that was not detected prior to importation, is identified by a qualified fish pathologist, the registered aquaculturist must comply with existing regulations in Section 245 and subsection 236(c)(5), which require the immediate destruction of the

# Staff Summary for October 9-10, 2024 For Background Purposes Only

specimens or exporting them out of the state within an amount of time determined by the Department.

For a high-level summary of the rulemaking intent, see the Department memo in Exhibit 1. More details on the proposal, rationale for each draft proposed provision, and statutory background can be found in the draft initial statement of reasons (Exhibit 2). The proposed regulation changes are not currently scheduled to be vetted by any of the Commission's three committees or by staff with potentially affected stakeholders.

Today, the Department will provide a verbal overview of the draft proposed regulation changes and rationale.

#### Significant Public Comments (N/A)

#### Recommendation

**Department:** Authorize publication of a notice of intent to amend regulations as detailed in the draft initial statement of reasons.

#### **Exhibits**

- 1. Department memo, received September 27, 2024
- 2. Draft initial statement of reasons
- 3. Draft proposed regulatory language
- 4. Draft economic and fiscal impact statement (STD. 399) and addendum
- 5. Section 245, Title 14 (for background purposes only)

#### Motion

Moved by _	and seconded by	that the Commission authorizes
publication	of a notice of its intent to amend	Section 236 related to importing aquatic plants
and animals	s for research purposes.	

Signed original on file, received September 27, 2024

# Memorandum

Date: September 24, 2024

To: Melissa Miller-Henson

**Executive Director** 

Fish and Game Commission

From: Charlton H. Bonham

Director

Subject: Submission of Initial Statement of Reasons to Amend Section Title 14, California Code of Regulations, Re: Importation of Live Aquatic Plants and Animals For Research Purposes

The Department of Fish and Wildlife (Department) requests the Fish and Game Commission (Commission) authorize publishing notice of its intent to amend section 236 of Title 14, California Code of Regulations to allow for the importation of live aquatic plants by registered aquaculturist for the purpose of research including when a disease or pathogen has been detected in the shipment prior to importation. Authorization of the request to publish notice at the October 9-10, 2024, Commission meeting would allow for potential adoption at the December 11-12, 2024, Commission meeting.

The proposed changes to regulation will improve the process to import live aquatic plants and animals for the purpose of research. The regulations will limit the use of importation to closed facilities that prevent release, and with no intent to outplant or offer for sale. The registered aquaculturist will be required to maintain all the aquatic plants or animals identified in the permit in a fully enclosed system that does not have an outlet into the waters of the state.

If you have any questions regarding this item, contact Dr. Craig Shuman, Marine Regional Manager, at (805) 568-1246. The public notice for this rulemaking should identify Kirsten Ramey the Department's point of contact. Their contact information is (707) 599-0769 or <a href="mailto:R7RegionalMgr@wildlife.ca.gov">R7RegionalMgr@wildlife.ca.gov</a>.

ec: Chad Dibble, Deputy Director Wildlife and Fisheries Division

Jay Rowan, Chief Fisheries Branch

Melissa Miller-Henson, Executive Director Fish and Game Commission September 24, 2024 Page 2

Craig Shuman, D. Env., Region Manager Marine Region

Randy Lovell, Aquaculture Coordinator Wildlife and Fisheries Division

Nathan Goedde, Assistant Chief Counsel Office of General Counsel

Eric Kord, Assistant Chief Law Enforcement Division

Crystal D'Souza, Attorney Office of General Counsel

Garrett Wheeler, Attorney Office of General Counsel

Ona Alminas, Env. Program Manager Regulations Unit

David Thesell, Deputy Executive Director Fish and Game Commission

Susan Ashcraft, Marine Adviser Fish and Game Commission

David Haug, Analyst Fish and Game Commission

# § 245. Aquaculture Disease Control Regulations. (For background purposes only)

- (a) General Conditions.
- (1) All fish inspections and examinations for diseases/pathogens shall be conducted in accordance with the most recent edition of "Procedures for Detection and Identification of Certain Fish Pathogens" published by the Fish Health Section of the American Fisheries Society (FHS Blue Book). All such inspections and examinations shall be conducted by a fish pathologist.
- (2) When diseases/pathogens are identified by a fish pathologist in aquatic plants or animals in an aquaculture facility, or in transit to or from such a facility, or in animals intended to be imported into the state, pursuant to Section 236 of these regulations, which require restrictive action by the department, the owner or consignee involved shall be notified by the department immediately. The owner or consignee may accept the original identification or may request that the department seek confirmation of the identification by another fish pathologist.
- (3) Upon confirmation, if requested, or acceptance of the identification of any listed disease/pathogen which requires restrictive action by the department as set forth in subsection (c), a compliance agreement describing the action to be taken may be drawn up between the owner and the director. The department shall commence negotiation of the terms of the compliance agreement within 48 hours after acceptance or confirmation as defined in subsection (b). The agreement must be signed by the owner and the director within 30 days of acceptance or confirmation. If the compliance agreement is not signed within 30 days, a quarantine as specified in Fish and Game Code Section 15505 may be imposed while the owner appeals to the commission. The agreement shall be designed in consultation with the Aquaculture Disease Committee to bring the least amount of economic hardship possible to the affected party while affording maximum protection to other growers and the fishery resources of the State.
- (4) If at any time a fish pathologist identifies one or more pathogens listed in this section anywhere within the State of California, he must immediately report the identification to the director of the department.
- (5) Methods for disposal of aquatic plants and animals and for disinfection of aquaculture equipment and facilities shall be specified in the compliance agreement in accordance with the disease category and the threat to other aquatic plant or animal life or aquaculture facilities.
- (6) Any live aquatic plants, animals or eggs originating outside California shall be certified by a fish pathologist as free of subsection (c) listed diseases/pathogens before a permit for importation is issued.

- (7) Anyone interested in conducting research on those diseases/pathogens designated as catastrophic must submit a written research proposal to the director of the department and obtain written approval from the director before the pathogen is brought to their facility. Anyone denied approval pursuant to this subsection may appeal such denial to the commission.
- (8) Upon identification of a disease/pathogen which presents a threat to the aquaculture industry or aquatic animal or plant life, but which is not listed in this section, the director of the department shall immediately consult, by phone if necessary, with the Aquaculture Disease Committee, impose an immediate holding action and develop a plan of action, which may include prohibiting an intended importation of aquatic plants or animals infected by the disease.

#### (b) Definitions.

- (1) Compliance Agreement. A written agreement between the director of the department and the owner or consignee of the diseased or infected aquaculture product which outlines the steps for disposal of the infected aquatic plants or animals and the procedures, both chemical and mechanical, for clean up of the facility.
- (2) Confirmation. The second identification of a disease agent from the original sample or source by another fish pathologist.
- (3) Disposal. The destruction or marketing of animals by methods prescribed in a compliance agreement.
- (4) Eradication. The elimination of disease agents.
- (5) Fish Pathologist. A department veterinarian or fish pathologist, or a fish pathologist certified by the Board of Certification of the Fish Health Section of the American Fisheries Society pursuant to their guidelines adopted effective January 1, 1982 or a fish health specialist recognized by a state or federal governmental authority and approved by the department.
- (6) Immediate Holding Action. A prohibition of moving any plant or animal from an aquaculture facility for up to 30 days.
- (7) Other Holding Action. Restrictions outlined in the compliance agreement on plant or animal movement to specific markets, watersheds or geographic areas deemed necessary by the department to protect other aquaculture facilities and the aquatic plants and animals of the State.
- (8) Q Diseases. Diseases for which there is so little information they cannot be given a permanent classification.

- (9) Disease. An abnormal condition of an organism as a consequence of infection by a pathogen, that impairs normal physiological function.
- (10) Pathogen. A biological agent that has the potential to cause disease.
- (11) Infection. Invasion of an organism by a pathogenic biological agent.
- (c) Disease Categories. The diseases/pathogens of concern are grouped in four categories as to their seriousness and the specific action to be taken when diagnosed.
- (1) Significant Diseases/Pathogens. On identification by a fish pathologist and confirmation, if requested, of any of these diseases/pathogens, the director shall immediately consult, by phone if necessary, with the Aquaculture Disease Committee and shall impose an immediate holding action, other holding action or no restrictions as the director in consultation with the Aquaculture Disease Committee may deem necessary.
- (A) Viruses
- 1. White Sturgeon Iridiovirus (WSIV).
- (B) Bacteria
- 1. Enteric Redmouth (ERM) Yersinia ruckeri.
- 2. Furunculosis Aeromonas salmonicida.
- 3. Vibriosis in finfish raised in freshwater *Vibrio* spp.
- (C) Parasites
- 1. Copepod Lernaea spp., Salmincola spp., and Ergasilus spp.
- 2. Oyster Disease (MSX) Haplosporidium nelsoni.
- 3. Sabellid Polychaete Fan Worm Terebrasabella heterouncinata.
- (D) Fungi
- 1. Ichthyophonus *lchthyophonus hoferi*.
- (E) Dinoflagellate Algae
- 1. Oyster Perkinsosis Perkinsus marinus.
- (2) Serious Diseases. On identification by a fish pathologist of any of these diseases, the director shall immediately consult, by phone if necessary, with the Aquaculture Disease Committee and shall impose an immediate holding action until confirmation, if requested, is obtained; then the action will be disposal or other holding action the

director in consultation with the Aquaculture Disease Committee may deem necessary, as specified in the compliance agreement.

- (A) Viruses
- 1. Koi Herpes Virus (KHV).
- 2. Largemouth Bass Virus (LMBV).
- (B) Bacteria
- 1. Bacterial Kidney Disease (BKD) Renibacterium salmoninarum.
- (C) Parasites
- 1. Bonamiasis of Oysters Bonamia spp.
- 2. Ceratomyxosis Ceratomyxa shasta.
- 3. Microsporiasis Pleistophora ovariae.
- 4. Proliferative Kidney Disease (PKD) Tetracapsuloides bryosalmonae
- 5. Seaside Disease Haplosporidium costale.
- 6. Whirling Disease Myxobolus cerebralis.
- (3) Catastrophic Diseases. On identification by a fish pathologist of any of these diseases, the director shall immediately consult, by phone if necessary, with the Aquaculture Disease Committee and shall impose an immediate holding action until confirmation, if requested, is obtained; then other holding action, disposal and eradication shall be required, as specified in the compliance agreement.
- (A) Viruses
- 1. Abalone Herpesvirus.
- 2. Channel Catfish Virus (CCV).
- 3. Infectious Hematopoietic Necrosis Virus (IHNV).
- 4. Infectious Pancreatic Necrosis Virus (IPNV).
- 5. Infectious Salmon Anemia Virus (ISAV).
- 6. Spring Viremia of Carp Virus (SVCV) Rhabdovirus carpio.
- 7. Viral Hemorrhagic Septicema Virus (VHSV).
- (B) Bacteria
- 1. Salmon Rickettsiosis *Piscirickettsia salmonis*.
- (C) Parasites
- 1. Marteilioides chungmuensis.

- (4) Q Diseases. On identification by a fish pathologist and confirmation, if requested, of any of these diseases, the director shall immediately consult, by phone if necessary, with the Aquaculture Disease Committee and shall impose an immediate holding action pending determination of a course of action for diseases in this classification.
- (A) Viruses
- 1. Herpesvirus salmonis (HPV).
- 2. Viral Erythrocytic Necrosis Virus (VENV).
- (B) Bacteria
- 1. Edwardsiella ictaluri.
- (C) Parasites
- 1. Denman Island Disease of Oysters Mikrocytos mackini.
- (d) Aquatic Diseases and Host Organisms. Pursuant to Section 15500 of the Fish and Game Code, the commission has compiled a list of diseases and parasites and the aquatic plants and animals they are known to infect or parasitize. Infected plants or animals are considered detrimental to the aquaculture industry and to wild stocks of aquatic plants and animals.

## Disease/Pathogen

- (1) Viruses
- (A) Abalone Herpesvirus
- (B) Channel Catfish Virus (CCV)
- (C) Herpesvirus salmonis (HPV)
- (D) Infectious Hematopoietic Necrosis Virus (IHNV)
- (E) Infectious Pancreatic Necrosis Virus (IPNV)
- (F) Infectious Salmon Anemia Virus (ISAV)
- (G) Koi Herpes Virus (KHV)
- (H) Largemouth Bass Virus (LMBV)
- (I) Spring Viremia of Carp Virus (SVCV) Rhabdovirus carpio
- (J) Viral Erythrocytic Necrosis Virus (VENV)
- (K) Viral Hemorrhagic Septicemia Virus (VHSV)
- (L) White Sturgeon Iridovirus (WSIV)
- (2) Bacteria
- (A) Bacterial Kidney Disease (BKD) Renibacterium salmoninarum
- (B) Enteric Redmouth (ERM) Yersinia ruckeri
- (C) Edwardsiella ictaluri
- (D) Furunculosis Aeromonas salmonicida
- (E) Salmon Rickettsiosis *Piscirickettsia salmonis*

- (F) Vibriosis in finfish raised in freshwater *Vibrio* spp.
- (3) Parasites
- (A) Bonamiasis of Oysters *Bonamia* spp.
- (B) Ceratomyxosis Ceratomyxa shasta
- (C) Copepod Lernaea spp., Salmincola spp., and Ergasilus spp.
- (D) Denman Island Disease Mikrocytos mackini
- (E) Marteilioides chungmuensis
- (F) Microsporiasis Pleistophora ovariae
- (G) Oyster Disease (MSX) Haplosporidium nelsoni
- (H) Proliferative Kidney Disease (PKD) Tetracapsuloides bryosalmonae
- (I) Sabellid Polychaete Fan Worm Terebrasabella heterouncinata
- (J) Seaside Disease *Haplosporidium costale*
- (K) Whirling Disease Myxobolus cerebralis
- (4) Fungi
- (A) Ichthyophonus Ichthyophonus hoferi
- (5) Dinoflagellate Algae
- (A) Oyster Perkinsosis Perkinsus marinus

# 236 PSOR Importation for Research - email in lieu

From: Alminas, Ona
To: FGC; Haug, David
Wed 11/27/2024 2:02 PM
Greetings David and FGC staff:
With regards to the rulemaking, "236 Importation of live aquatic plants and animals for research purposes" which was noticed October 11, 2024, there have been no substantive comments received, there are no amendments to the regulatory text, or additional information gathered for this rulemaking, therefore a full Pre-Adoption Statement of Reasons is not necessary in advance of the December 11-12, 2024 meeting, where is the rulemaking is proposed for adoption.
Regards,
Ona Alminas
FISH and WILDLIFE
Ona Alminas, M.S. (she/her)
Regulations Unit Manager
715 P Street, 17 <sup>th</sup> Floor
Sacramento, CA 95814

# State of California Fish and Game Commission Initial Statement of Reasons for Regulatory Action

# Amend Section 236 Title 14, California Code of Regulations Re: Importation for Research

I. Date of Initial Statement of Reasons: August 28, 2024

II. Dates and Locations of Scheduled Hearings

(a) Notice Hearing

Date: October 9-10, 2024 Location: Sacramento, CA

(b) Discussion/ Adoption Hearing

Date: December 11-12, 2024 Location: Sacramento, CA

III. Description of Regulatory Action

(a) Statement of Specific Purpose of Regulatory Change and Factual Basis for Determining that Regulation Change is Reasonably Necessary

All section references are within the California Code of Regulations, Title 14, unless otherwise noted.

#### Introduction

California state laws require an importation permit to import most live aquatic plants and animals. These permits ensure activities are carried out to safeguard wildlife as well as promote local and state conservation efforts. Importation of live aquatic plants and animals into California requiring a permit may be considered for various reasons, including research, aquaculture purposes, and live seafood markets for human consumption. The importation permits are designed to reduce the risk of importation of certain plants that can pose a threat to native wildlife, aquaculture, and other aquatic resources or ecosystems. It is critical to conduct research in closed systems with appropriate safeguards to prevent possible catastrophic impacts in the event of escape or release to the environment.

There is a biological and public trust need for scientific research to respond to the challenges presented by diseases, pathogens, or parasites, and uncover solutions that can halt the deterioration and improve the condition of aquatic and other ecosystems. However, existing state regulations limit the scope of importation for research purposes. The proposed action is designed to allow the importation of live aquatic plants and animals into California by a registered aquaculturist for the purposes of research, including when a disease, pathogen, or parasite has been detected in a shipment prior to importation.

The proposed changes to regulation will allow for importation of live aquatic plants and animals for the purpose of research, subject to approval and permit conditions specified by Department. The regulations will restrict importation to closed facilities that prevent release and with no intent to outplant, or offer for sale. The registered aquaculturist will be required to maintain all the aquatic plants or animals identified in the permit in a fully enclosed system that does not have an outlet into the waters of the state. The proposed changes will serve as an avenue for facilitating research in controlled environments, and address inconsistencies with allowances for catastrophic or other disease types (described in subsection 245(c)), and to allow research under safe and prescribed conditions.

#### **Statutory and Regulatory Setting**

Several Fish and Game Code (F&G Code) sections pertain to the proposed regulatory changes, as follows:

F&G Code Section 2150, subdivision (e) states that "...any university, college, governmental research agency, or other bona fide scientific institution, as defined in regulations adopted by the Commission, engaging in scientific or public health research is exempt from any permit requirement pursuant this chapter except for animals whose importation, transportation, or possession is determined by the Department, in cooperation with the Department of Food and Agriculture, to be detrimental or cause damage to agriculture, native wildlife, or public health or safety." Although diseased organisms may be considered detrimental or cause the kind of damage articulated here, and therefore not be exempt from this chapter's permit requirement, the legislature provides more specific disease-related guidance with F&G Code Section 2270.

F&G Code Section 2270 states that "...it is unlawful for any person to receive, bring, or cause to be brought into this state, for the purposes of propagation, any fish, reptile, amphibian, or aquatic plant from *any place* wherein any infected, diseased, or parasitized fish, reptile, amphibian, or aquatic plants *are known to exist*." However, without clarity that defines how widely "any place" would apply to such restrictions, F&G Code Section 2270.5 was added. F&G Code Section 2270.5 states that "...Section 2270 for importation of an infected, diseased, or parasitized live aquatic plant or animal does not apply if imported by a registered aquaculturist if the importation has been approved by the Department pursuant to F&G Code Section 15600." This section provides the Department a way to distinguish or interpret the boundaries of what is meant by "any place" where problems "are known to exist," so that aquaculture importations of healthy organisms could be constrained by written approvals (i.e: permit conditions) within a reasonable level of risk management.

F&G Code Section 15600, subdivision (a) states "No live aquatic plant or animal may be imported into this state by a registered aquaculturist without the prior written approval of the department pursuant to the regulations adopted by the commission." This section requires written approval for the importation of live organisms, including live aquatic plants, by a registered aquaculturist. This is only partially implemented by way of the importation permit described in Section 236, Title 14 that the proposed changes aim to fix.

Two Title 14, CCR sections are relevant to the proposed changes.

Section 236 outlines provisions for importation of live aquatic plants and animals, including those aquatic plants and animals which do not need an importation permit (subsection 236(b)), application, fees, and inspection processes (subsections 236(c)(1) through(c)(4)); process for destruction or export from the state of any lot or load of aquatic plants and animals found to be diseased, parasitized or to contain species not authorized by the importation permit (subsection 236(c)(5)); issuance of permits on a long-term basis for certain species specified in 236(c)(6)(A) through (I), importation of salmon eggs (subsection (c)(7)); and requirement for lawful possession to import (subsection (c)(8)).

Section 245 outlines the regulations for disease control for aguaculture facilties. Subsection 245(a) outlines general conditions for inspections, steps to take in the event of disease or pathogen detection in aquaculture stocks by a fish pathologist, process to establish a compliance agreement in the event of detection of a listed [under subsection 245(c)] disease/pathogen, and reporting. Relevant to the proposed changes, subsection 245(a)(7) states that anyone interested in conducting research on diseases/pathogens designated as catastrophic must submit a written research proposal to the director of the department and obtain written approval from the director before the pathogen is brought to their facility. However, this section is limited to only diseases/pathogens categorized as "catastrophic" and does not allow for research to be conducted on other disease/pathogen categories. Subsection 245(b) defines several terms, including "compliance agreement," "disposal," "disease," and "pathogen." Subsection 245(c), describes four categories of diseases/pathogens of concern as to their seriousness and the specific action to be taken when diagnosed. The four categories are: Significant Diseases/Pathogens, Serious Diseases, Catastrophic Diseases, and Q Diseases. Subsection 245(d) describes aquatic diseases and host organisms.

### **Background**

F&G Code Sections 2270.5 and 15600 do not prohibit the Department from issuing an importation permit for registered aquaculturists to import, and hold in possession, organisms from locations where disease, pathogens, or parasites have been detected, subject to Department approval. This proposed regulation aims to provide clarification between apparent contrasts in sections 236 and 245 for importation of live aquatic plants, in addition to live aquatic animals, solely for research purposes when the aquatic plant or animal is known to have a disease or pathogen.

Current regulations require certain procedures to take place if there is a disease or pathogen detection in a shipment of aquatic plants or animals and appears to only encompass after-the-fact discoveries of diseases or pathogens. Section 236 addresses what is and is not allowed, and with this change, may now be under certain conditions, brought into the state. Section 245 addresses what to do when a disease is detected in aquaculture stocks that are already present in the state. Subsequent actions or

requirements by the Department vary depending on the disease/pathogen detected, and whether it is a threat to the aquaculture industry or aquatic animal or plant life.

There is a lack of clarity between subsection 236(c) and Section 245 regarding in what circumstances an aquaculturist would end up with a compliance agreement rather than the required immediate destruction of aquatic plants or animals per subsection 236(c). This proposed regulation clarifies that when the registered aquaculturist is intentionally bringing in plants or animals with diseases/pathogens for research purposes, the restrictions otherwise imposed for disease detection do not apply, subject to conditions set by the Department.

There is currently no mechanism to allow registered aquaculturists to import and conduct research on aquatic plants or animals that are known to have a disease or pathogen prior to shipment. In the interest of addressing this gap in regulations, with allowances made for catastrophic diseases (and other disease categories), the proposed regulations will limit the use of importation for the purposes of research to closed facilities that prevent release, and with no intent to outplant, or offer for sale. The registered aquaculturist will be required to maintain all the aquatic plants or animals identified in the permit in a fully enclosed system that does not have an outlet into the waters of the state.

# **Proposed Amendments to Regulations**

Section 236. Importation for Research

The proposed changes to regulation will allow for importation of species for research in closed facilities that prevent release, with no intent to outplant or offer for sale.

Amend subsection 236(c)(2): to add "aquatic plants" to the existing exceptions that currently only apply to live aquatic animals. This change is necessary to fully implement F&G Code Section 15600 for both aquatic plants and animals. Aquatic plants would then be included under "other species" referenced in 236(c)(7)(I) for clarity purposes. The reference to subsection 236(c)(6) is updated to 236(c)(7) with the re-numbering of (c)(6) to (c)(7) (described below).

Amend subsection 236(c)(5): to add the words "...except as otherwise provided in subsection 236 (c)(6)..." which points to the new added subsection (c)(6), and would not require destruction or export from the state of aquatic plants and animals that have been found to be diseased, parasitized, or contain a species not authorized. This change is necessary to accommodate the new subsection (c)(7).

#### Add subsection 236(c)(6):

establishes that a registered aquaculturist, solely for research purposes, may import
aquatic plants or animals, for which a disease or pathogen has been detected in the
shipment prior to importation, subject to written approval and permit conditions specified
by the department. This language is necessary to specify who is eligible to import live
aquatic plants and animals from infected, diseased, or parasitized areas solely for the
purpose of research. Because of the authority of F&G Code Sections 15600 and

2270.5, this can only be done by a registered aquaculturist via an importation permit. The Department must be able to provide permit conditions that minimize risk of such importations.

- This provision further specifies that, at minimum, the permit shall require the registered aquaculturist to maintain all aquatic plants or animals identified in the permit to be in a closed water system, for which an applicable definition is referenced from subsection 671.7(a)(1). This referenced definition states that a... "closed-water system" is defined as a closed system or systems that treats holding water and sediments sufficiently to ensure against the release of live organisms, including parasites, pathogens and viruses, into the waters of the state. For purposes of this section, municipal treated sewage systems are not considered waters of the state." Referencing this subsection in the proposed regulation is necessary to not duplicate a definition in Section 236. It accounts for a gap in the regulations for registered aquaculturists to be forthright in their purpose while allowing Department to provide conditions as safeguards for transmission outside of a closed system.
- The language, "If a disease or pathogen listed in Section 245(c) of these regulations, not originally detected prior to importation, is identified by a fish pathologist, the registered aquaculturist shall comply with subdivision (c)(5) and Section 245 of these regulations." This provision is necessary to provide guidance for the potential scenario of contamination after importation of the imported aquatic plant or animal with a disease or pathogen listed in subsection 245(c). This contamination following importation into the state would then follow existing regulations. A fish pathologist is specifically responsible for identification of a disease or pathogen for consistency with subsection 245(a).

Re-number and amend subsection 236(c)(7): To accommodate for the added subsection 236(c)(6), this subsection is re-numbered to 236(c)(7). As with amendment to subsection 236(c)(2), the proposal to add "aquatic plants" to the existing exceptions that currently only apply to live aquatic animals is necessary to fully implement F&G Code Section 15600 for both aquatic plants and animals. Aquatic plants would then be included under "other species" referenced in 236(c)(7)(I) for clarity purposes.

Re-number subsection 236(c)(7) to (c)(8), and (c)(8) to (c)(9). These changes are necessary to accommodate the added subsection 236(c)(6).

Add Section 236(d): establishes an enforcement clause for the terms and special conditions of an importation permit issued pursuant to Section 236. This addition is necessary for enforcement of issued importation permits that include terms and special conditions surrounding the importation. This added language combined with subsection 236(c) makes it very clear that violation of permit terms and special conditions could result in an enforcement citation, or more serious consequences.

Remove reference: F&G Code Section 2191 from the list of references, as it no longer exists in the F&G Code.

(b) Goals and Benefits of the Regulation

This proposed regulation is necessary to address inconsistencies between allowances made for catastrophic diseases (and other disease categories) and allowances forresearch under prescribed conditions. Overall, the goal of this proposed action is to allow the importation of live aquatic plants into California by a registered aquaculturist for the purposes of research, including when a disease or pathogen has been detected in the shipment prior to importation.

- (c) Authority and Reference Sections from Fish and Game Code for Regulation
  - § 236 Authority cited: Sections 1050, 2118, 6401, 15004, 15600 and 15601, Fish and Game Code.

Reference: Sections 2116-2190, 2270-2272 and 3201-3204, Fish and Game Code.

- (d) Specific Technology or Equipment Required by Regulatory Change. None
- (e) Identification of Reports or Documents Supporting Regulation Change None.
- (f) Public Discussions of Proposed Regulations Prior to Notice Publication None.
- IV. Description of Reasonable Alternatives to Regulatory Action
  - (a) Alternatives to Regulation Change

No alternatives to this regulatory change were identified by or brought to the attention of Commission staff that would have the same desired regulatory effect. Changes to allow for the research of diseased aquatic plants and animals under safe and prescribed conditions cannot be accomplished by different means.

(b) No Change Alternative

Without the proposed regulatory change, the opportunity to allow research of diseased aquatic plants and animals under safe and prescribed conditions will not exist.

(c) Description of Reasonable Alternatives that Would Lessen Adverse Impact on Small Business

There is no alternative that would lessen the burden on Small Business. The proposed change will remove the competitive disadvantages for businesses currently operating within the state that are currently unable to import species without this regulatory change.

V. Mitigation Measures Required by Regulatory Action

The proposed regulatory action will have no negative impact on the environment; therefore, no mitigation measures are needed.

VI. Impact of Regulatory Action

The potential for significant statewide adverse economic impacts that might result from the

proposed regulatory action has been assessed, and the following initial determinations relative to the required statutory categories have been made:

- (a) Significant Statewide Adverse Economic Impact Directly Affecting Businesses, Including the Ability of California Businesses to Compete with Businesses in Other States The Commission does not anticipate that the proposed action will have significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. The proposed change will remove the competitive disadvantages for businesses currently operating within the state that are currently unable to import species without this regulatory change.
- (b) Impact on the Creation or Elimination of Jobs Within the State, the Creation of New Businesses or the Elimination of Existing Businesses, or the Expansion of Businesses in California; Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The Commission does not anticipate adverse impacts on the creation or elimination of jobs within the state. The Commission does not anticipate adverse impacts on the creation of new business, the elimination of existing businesses, or the expansion of businesses in California. The proposed changes are to allow for a more streamlined and efficient process for importation of live aquatic plants and animals for the purpose of research and limit the use of importation to closed facilities that prevent release and with no intent to outplant or offer for sale. Under the proposed action a registered aquaculturist will be required to maintain all aquatic plants or animals identified in the permit in a fully closed system that does not have an outlet into the waters of the state in order to prevent the specified pathogen or disease from entering the environment. The Commission expects at least one aquaculturist to begin operating in the state as a result of the proposed regulations but does not expect demand for goods and services related to the aquaculture industry to significantly change. The Commission does not anticipate that the proposed regulation will negatively impact the demand for labor, nor induce the elimination nor the expansion of businesses in California. The Commission does not anticipate any benefits to the health and welfare of California residents or to worker safety. The Commission anticipates benefits to the State's environment indirectly through increased control of importations, which may prevent the introduction of pathogens into the state.

(c) Cost Impacts on a Representative Private Person or Business

The Commission anticipates that the proposed regulatory action will have minor economic impacts on businesses and small businesses that operate as aquaculturists and seek to import specimens with non-catastrophic diseases or pathogens; however, these are not new costs imposed by the proposed regulatory action but rather the current cost of compliance that aquaculturists seeking to import specimens already face as part of the permitting process. The proposed regulatory action removes a prohibition on the importation of species identified as being infected with non-catastrophic diseases or pathogens to allow the research of diseased aquatic plants under safe and prescribed conditions. The costs for diagnostics & testing services for pathogens required by

applicants for an importation license under current regulations is approximately \$4,000-\$10,000 depending on the need for repeated testing, with a median cost of \$8,000. Currently most aquaculturists happen to qualify as small businesses, but the sector is not limited to small businesses in terms of who may enter the market. In 2024 there are approximately 130 registered aquaculture facilities in the state, with some of those facilities operated by the same company. Only a fraction of them will likely conduct the kind of research being contemplated for approval under the proposed regulatory action, and the Commission expects the percentage of affected aquaculturists to be 15-20%, which would create an approximate annual cost of \$156,000-\$208,000 based on the median testing cost of \$8,000. However, this testing cost is the same cost that all other importers face when importing a species into the state and does not represent a new cost created or imposed by these regulations.

- (d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

  None
- (e) Nondiscretionary Costs/Savings to Local Agencies:

None

(f) Programs Mandated on Local Agencies or School Districts:

None

(g) Costs Imposed on Any Local Agency or School District that is Required to be Reimbursed Under Part 7 (commencing with Section 17500) of Division 4, Government Code:

None

(h) Effect on Housing Costs:

None

- VII. Economic Impact Assessment
  - (a) Effects of the Regulation on the Creation or Elimination of Jobs Within the State

The Commission does not anticipate significant impacts on the creation of new jobs or the elimination of jobs from the 130 existing registered aquaculture facilities. The proposed regulation may prompt new aquaculturists to enter the industry and enable existing aquaculturists to seek the permit to conduct research under the new provisions, but the extent to which this may happen is unknown.

(b) Effects of the Regulation on the Creation of New Businesses or the Elimination of Existing Businesses Within the State

The Commission does not anticipate adverse impacts on the creation of new business or the elimination of the 130 existing aquaculture organizations. The proposed regulation may prompt new aquaculturists to enter the industry and enable existing aquaculturists to seek the permit to conduct research under the new provisions, but the extent to which this may happen is unknown.

(c) Effects of the Regulation on the Expansion of Businesses Currently Doing Business Within the State

The Commission does not anticipate significant impacts on the expansion of businesses in California. There is one aquaculturist that is expected to enter the market upon the adoption of these regulations, and the expected cost impact from increased testing is expected to only affect 15-20% of aquaculturists engaged in the type of research specified in the proposed regulations.

(d) Benefits of the Regulation to the Health and Welfare of California Residents

None

(e) Benefits of the Regulation to Worker Safety

None

(f) Benefits of the Regulation to the State's Environment

The Commission anticipates benefits to the state's environment indirectly through increased control of importations, the containment of diseases or pathogens in research, and the benefits derived from disease or pathology research improving diagnoses, preventative measures, and treatments.

(g) Other Benefits of the Regulation

None

#### Informative Digest/Policy Statement Overview

There is a biological and public trust need for scientific research to respond to the challenges presented by diseases, pathogens, or parasites, and uncover solutions that can halt the deterioration and improve the condition of aquatic and other ecosystems. However, existing state regulations limit the scope of importation for research purposes. The goal of this proposed action is to allow the importation of live aquatic plants and animals into California by a registered aquaculturist for the purposes of research, including when a disease, pathogen, or parasite has been detected in a shipment prior to importation.

The proposed regulatory amendments would allow for importation of live aquatic plants and animals for the purpose of research, subject to approval and permit conditions specified by the Department of Fish and Wildlife (Department). The regulations would restrict importation to closed facilities that prevent release and with no intent to outplant or offer for sale. The registered aquaculturist will be required to maintain all aquatic plants or animals identified in the permit in a fully closed system that does not have an outlet into the waters of the state. The proposed changes will serve as an avenue for facilitating further research of diseases in controlled environments, and address inconsistencies with allowances for catastrophic or other disease types and to allow research under safe and prescribed conditions.

#### **Proposed Amendments**

In order to improve the permitting process and oversight of importation of live aquatic plants and animals for the purpose of research, the Department proposes amendment to Section 236 as follows:

- Amend Section 236(c)(2): to add "aquatic plants" to the existing exceptions that currently only apply to live aquatic animals to fully implement Fish and Game Code Section 15600 for both aquatic plants and animals.
- Amend Section 236(c)(5): to add the words "...except as otherwise provided in subsection 236 (c)(6)..." which points to the new added subsection (c)(6), and would not require destruction or export from the state of aquatic plants and animals that have been found to be diseased, parasitized, or contain a species not authorized.
- Add Section 236(c)(6):
  - Establishes that a registered aquaculturist, solely for research purposes, may import aquatic plants or animals for which a disease or pathogen has been detected in the shipment prior to importation, subject to written approval and permit conditions specified by the department.
  - Requires the registered aquaculturist to maintain all aquatic plants or animals identified in the permit to be in a closed water system, for which an applicable definition is referenced from subsection 671.7(a)(1) of Title 14, California Code of Regulations.
  - Specifies that if a disease or pathogen listed in Section 245(c) of these regulations, not originally detected prior to importation, is identified by a fish pathologist, the registered aquaculturist shall comply with subdivision (c)(5) and Section 245 of these regulations.

- Amend Section 236(c)(7): Re-number and amend subsection 236(c)(7) to add "aquatic plants" to the existing exceptions that currently only apply to live aquatic animals to fully implement Fish and Game Code Section 15600 for both aquatic plants and animals.
- Re-number subsection 236(c)(7) to (c)(8), and (c)(8) to (c)(9).
- Add Section 236(d): establishes an enforcement clause for the terms and special conditions of an importation permit issued pursuant to Section 236.

#### Benefits of the regulations

Existing regulatory mechanisms regarding diseased aquatic plants seem to only encompass after-the-fact discoveries of diseases, but no mechanism currently exists to allow research to be conducted on aquatic plants and animals that are known to be infected. This proposed regulation is necessary for the interest of addressing inconsistencies with allowances made for catastrophic diseases (and other disease categories) and allowing research under prescribed conditions. This regulation provides potential indirect benefits to the state's environment through increased control of importations, the containment of diseases or pathogens in research, and the benefits derived from disease or pathology research that may include improving diagnoses, preventative measures, and treatments. Overall, the goal of this proposed action is to allow the importation of live aquatic plants and animals into California by a registered aquaculturist for the purposes of research, including when a disease or pathogen has been detected in the shipment prior to importation.

# Evaluation of incompatibility with existing regulations

The proposed regulations are neither inconsistent nor incompatible with existing state regulations. Article IV, Section 20 of the State Constitution specifies that the Legislature may delegate to Commission such powers relating to the protection and propagation of fish and game as the Legislature sees fit. The Legislature has delegated to the Commission the power to adopt regulations governing aspects of importation of live aquatic plants and animals by a registered aquaculturist (California Fish and Game Code Section 15600), an authority that no other state agency has. The Commission has reviewed its own regulations and finds that the proposed regulations are consistent with other live aquatic plant and animal importation regulations in Title 14, CCR, and therefore finds that the proposed regulations are neither inconsistent nor incompatible with existing state regulations.

#### **Proposed Regulatory Language**

Section 236, Title 14 CCR, is amended as follows:

## § 236. Importation of Live Aquatic Plants and Animals.

The provisions of this section shall apply to the importation of all live aquatic plants and animals.

- (a) No person shall import into this state any prohibited species of live aquatic plant or animal listed pursuant to Section 2118 of the Fish and Game Code or Section 671 of these regulations unless specifically authorized by the commission.
- (b) Unless specifically prohibited by these regulations, plants and animals within the following groups may be imported without an importation permit from the department:
- (1) Mollusks and crustaceans intended to go directly into the seafood market and which will not be placed into the waters of the state nor placed in waters which are discharged to waters of the state.
- (2) Live ornamental tropical marine or freshwater plants or animals that are not utilized for human consumption or bait purposes, are maintained in closed systems for personal, pet industry or hobby purposes, and which will not be placed in waters of the state.
- (3) Brine shrimp.
- (c) With the exception of those importations described in Section 236(a) and (b), live aquatic plants and animals may be imported into this state only in accordance with the following terms and conditions:
- (1) A standard importation permit signed by the director or his agent is required, and no shipment into the state may be made prior to the issuance of the permit authorizing the shipment or shipments. The department shall charge a fee of \$25.00 for issuing each permit. Fees charged for inspections shall be independent of the fees charged for issuing permits.
- (2) With the exceptions of the live aquatic <u>plants and</u> animals listed in subsection 236(c)(67), a permit is required for each lot or load, and each shipment must be accompanied by the original copy of the importation permit. Unless otherwise authorized, the person who is to receive any shipments of aquatic plants and animals shall apply to the department for this importation permit.
- (3) Application for a standard importation permit shall be made on a form (Application for Standard Importation Permit, FG 789 (2/91), which is incorporated by reference herein) supplied by the department, as directed in Section 235(d) and shall reach the department's headquarters office at least 10 working days in advance of the probable arrival date of the shipment. A copy of the permit authorized by the director or his agent must accompany each load. If a change in date of shipment becomes necessary after a permit has been issued, the permittee shall notify the Aquaculture Development Section at least 5 days before the new date of shipment. Under special circumstances, the department may waive this 5-day notice requirement.

- (4) All live aquatic plants and animals imported into California may be inspected by the department, either at the place of entry into the state or at other locations suitable to the department. The person importing the aquatic plants or animals may be required to provide facilities for inspecting and sorting them, and may be required to pay inspection costs, including salary and travel expenses of the inspector.
- (5) Except as otherwise provided in subsection 236(c)(6), Anyany lot or load of aquatic plants and animals found by the inspector to be diseased, parasitized or to contain species not authorized by the importation permit must be immediately destroyed or transported out of California within a period of time specified by the department. In such cases, the importation permit is automatically revoked.
- (6) Notwithstanding subsection 236(c)(5) and Section 245 of these regulations, a registered aquaculturist, solely for research purposes, may import aquatic plants or animals, for which a disease or pathogen has been detected in the shipment prior to importation, subject to written approval and permit conditions specified by the department. At a minimum, the permit shall require the registered aquaculturist to maintain all the aquatic plants or animals identified in the permit in a closed water system as defined in Section 671.7(a)(1) of these regulations. If a disease or pathogen listed in subsection 245(c) of these regulations, not originally detected prior to importation, is identified by a fish pathologist, the registered aquaculturist shall comply with subsection 236(c)(5) and Section 245 of these regulations.
- (6)(7) In lieu of the permits specified in subsection 236(c)(1), long-term permits for the following aquatic <u>plants and</u> animals may be issued by the department for periods of up to one year. Application shall be made on a form (Application for Long-term Permit to Import Animals into California, FG 786 (2/91), which is incorporated by reference herein) supplied by the department. The department shall charge a fee for issuing each permit. See subsection 699(b) of these regulations for the fee for this permit.
- (A) Oyster, oyster larvae and oyster seed.
- (B) Ghost shrimps (*Callianassa spp*).
- (C) Mud shrimps (*Upogebia spp*).
- (D) Longjaw mudsuckers (Gillichthys mirabilis).
- (E) Red swamp crayfish (*Procambarus clarkii*).
- (F) Orconectes virilis.
- (G) Marine Annelid worms (Phylum Annelida).
- (H) Sacramento blackfish (Orthodon microlepidotus).
- (I) Other species under conditions which the department determines represent no significant risk to the fish and wildlife resources of the state.
- (7)(8) Importation of Salmonid Eggs. Applications to import eggs of fishes of the family salmonidae (trout, salmon and char) shall be accompanied by a health certificate signed by a person competent in the diagnosis of fish diseases stating that the hatchery or other sources of the eggs to be imported and the eggs themselves are free of the following diseases: infectious

pancreatic necrosis (IPN); bacterial kidney disease (BKD); infectious hematopoietic necrosis (IHN); and viral hemorrhagic septicemia (Egtved).

In questionable cases, the director of the department shall determine whether or not the person making the certification is technically qualified to do so.

- (8)(9) Only those aquatic plants and animals lawfully obtained in another state or country may be imported.
- (d) It is unlawful to violate the terms and special conditions of an importation permit issued pursuant to this section.

NOTE: Authority cited: Sections 1050, 2118, 6401, 15004, 15600 and 15601, Fish and Game Code. Reference: Sections 2116-21912190, 2270-2272 and 3201-3204, Fish and Game Code.

#### FCONOMIC IMPACT STATEMENT

	ECONOMIC IMI AC	ISTATEMENT	
DEPARTMENT NAME	CONTACT PERSON	EMAIL ADDRESS	TELEPHONE NUMBER
California Fish and Game Commission	David Thesell	fgc@fgc.ca.gov	916-201-6201
DESCRIPTIVE TITLE FROM NOTICE REGISTER OR F			NOTICE FILE NUMBER
Amend Section 236, Title 14 re: Importi	ng Live Aquatic Plants and A	Animals for Research Purposes	Z
A. ESTIMATED PRIVATE SECTOR COST IMPA	CTS Include calculations and assu	ımptions in the rulemaking record.	
Check the appropriate box(es) below to indicat	e whether this regulation:		
a. Impacts business and/or employees	e. Imposes reportin	g requirements	
b. Impacts small businesses	f. Imposes prescrip	tive instead of performance	
c. Impacts jobs or occupations	g. Impacts individu	als	
d. Impacts California competitiveness	h. None of the above	ve (Explain below):	
	Removes a pro	hibition on specific importatio	ns; see addendum.
· ·	-	ete this Economic Impact Statem I Impact Statement as appropriate	
2. The	estimates that the econo	mic impact of this regulation (which in	cludes the fiscal impact) is:
(Agency/Department)			
Below \$10 million			
Between \$10 and \$25 million			
Between \$25 and \$50 million			
Over \$50 million [If the economic impact as specified in Government	s over \$50 million, agencies are requi ent Code Section 11346.3(c)]	red to submit a <u>Standardized Regulator</u> y	<u>· Impact Assessment</u>
3. Enter the total number of businesses impacted			
Describe the types of businesses (Include nonp	rofits):		
Enter the number or percentage of total businesses impacted that are small businesses:			
4. Enter the number of businesses that will be cre	ated: elin	ninated:	
Explain:			
5. Indicate the geographic extent of impacts:	] Statewide		
	Local or regional (List areas):		
6. Enter the number of jobs created:	and eliminated:		
Describe the types of jobs or occupations impa	cted:		
<ol><li>Will the regulation affect the ability of California other states by making it more costly to produce</li></ol>		YES NO	
If YES, explain briefly:			
			-

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# **ECONOMIC IMPACT STATEMENT (CONTINUED)**

В.	<b>ESTIMATED COSTS</b> Include calculations and assumptions in the ru	ılemaking record.	
1.	What are the total statewide dollar costs that businesses and individua	als may incur to comply with this regulation over it	:s lifetime? \$
	a. Initial costs for a small business: \$		
	b. Initial costs for a typical business: \$		
		Annual ongoing costs: \$	
	d. Describe other economic costs that may occur:		
2.	If multiple industries are impacted, enter the share of total costs for each	ach industry:	
	If the regulation imposes reporting requirements, enter the annual co Include the dollar costs to do programming, record keeping, reporting, an		
4.	Will this regulation directly impact housing costs? YES	NO	
	If YES, enter the a	nnual dollar cost per housing unit: \$	
	Number of units:		
5.	Are there comparable Federal regulations? YES 1	NO	
l	Explain the need for State regulation given the existence or absence of	f Federal regulations:	
	Enter any additional costs to businesses and/or individuals that may be	e due to State - Federal differences: \$	
c.	<b>ESTIMATED BENEFITS</b> Estimation of the dollar value of benefits is a	not specifically required by rulemaking law, but en	couraged.
	Briefly summarize the benefits of the regulation, which may include as health and welfare of California residents, worker safety and the State		
2	Are the benefits the result of: specific statutory requirements, or	goals developed by the agency based on bro	ad statutory authority?
	Explain:	_	
3.	What are the total statewide benefits from this regulation over its lifet	ime? \$	
4.	Briefly describe any expansion of businesses currently doing business	within the State of California that would result from	m this regulation:
D.	<b>ALTERNATIVES TO THE REGULATION</b> Include calculations and a specifically required by rulemaking law, but encouraged.	assumptions in the rulemaking record. Estimation	of the dollar value of benefits is not
1.	List alternatives considered and describe them below. If no alternative	es were considered, explain why not:	

# **ECONOMIC IMPACT STATEMENT (CONTINUED)**

. Summarize the t	total statewide costs a	d benefits from this regulation and each alternative considered:
Regulation:	Benefit: \$	Cost: \$
Alternative 1:	Benefit: \$	Cost: \$
Alternative 2:	Benefit: \$	Cost: \$
•	* '	hat are relevant to a comparison
of estimated co	osts and benefits for t	is regulation or alternatives:
		onsider performance standards as an alternative, if a control of the control of t
actions or proce	edures. Were perform	nce standards considered to lower compliance costs? YES NO
Explain:		
MA IOR REGIII	ATIONS Include cal	ulations and assumptions in the rulemaking record.
- MAJON NEGOL		nmental Protection Agency (Cal/EPA) boards, offices and departments are required to
		following (per Health and Safety Code section 57005). Otherwise, skip to E4.
. Will the estimate	ed costs of this regu <b>l</b> a	on to California business enterprises <b>exceed \$10 million</b> ? YES NO
		If YES, complete E2. and E3 If NO, skip to E4
. Briefly describe	each a <b>l</b> ternative, or co	abination of alternatives, for which a cost-effectiveness analysis was performed:
Alternative 1: _		
Alternative 2: _		
(Attach addition	al pages for other alter	ntives)
For the regulati	ion, and each a <b>l</b> ternati	e just described, enter the estimated total cost and overall cost-effectiveness ratio:
_		Cost-effectiveness ratio: \$
		Cost-effectiveness ratio: \$
Alternative 2: T		Cost-effectiveness ratio: \$
exceeding \$50 r	million in any 12-mon	v have an estimated economic impact to business enterprises and individuals located in or doing business in Califor period between the date the major regulation is estimated to be filed with the Secretary of State through 12 month to be fully implemented?
YES [	<b>⋈</b> NO	
		<u>Standardized Regulatory Impact Assessment (SRIA)</u> as specified in d to include the SRIA in the Initial Statement of Reasons.
. Briefly describe	the following:	
The increase or	decrease of investme	in the State:
The incentive fo	or innovation in produ	cs, materials or processes:
The benefits of	the regulations in the	and but not limited to bonefits to the health safety, and welfare of California
		ng, but not limited to, benefits to the health, safety, and welfare of California senvironment and quality of life, among any other benefits identified by the agency:

# FISCAL IMPACT STATEMENT

A. FISCAL EFFECT ON LOCAL GOVER current year and two subsequent Fisca		through 6 and attach calculatio	ns and assumptions of fiscal impact for the
	rrent State Fiscal Year which are reimbu II B of the California Constitution and Se		
\$			
a. Funding provided in			
Budget Act of	or Chapter	, Statutes of	
b. Funding will be requested in	the Governor's Budget Act of		
	Fiscal Year:		
	rrent State Fiscal Year which are NOT re II B of the California Constitution and Se		
\$			
Check reason(s) this regulation is not r	eimbursable and provide the appropriate	e information:	
a. Implements the Federal mane	date contained in		
b. Implements the court manda			Court.
Case	of:	vs	
	people of this State expressed in their		
Date of Election	on:	_	
	pecific request from affected local entit		
Local entity(s) affect			
e. Will be fully financed from the	e fees, revenue, etc. from:		
Authorized by Sect	ion:	of the	Code;
f. Provides for savings to each a	ffected unit of local government which	will, at a minimum, offset any ac	dditional costs to each;
g. Creates, eliminates, or change	es the penalty for a new crime or infract	ion contained in	
3. Annual Savings. (approximate)			
\$			
	regulation makes only technical, non-sul	bstantive or clarifying changes to	current law regulations.
5. No fiscal impact exists. This regulat	ion does not affect any local entity or pro	ogram.	
6. Other. Explain			
_ · <u></u>			

# FISCAL IMPACT STATEMENT (CONTINUED)

1. Additional expenditures in the current State Fiscal Year. (Approximate)
\$
It is anticipated that State agencies will:
a. Absorb these additional costs within their existing budgets and resources.
b. Increase the currently authorized budget level for theFiscal Year
2. Savings in the current State Fiscal Year. (Approximate)
\$
3. No fiscal impact exists. This regulation does not affect any State agency or program.
4. Other. Explain
C. FISCAL EFFECT ON FEDERAL FUNDING OF STATE PROGRAMS Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fisca impact for the current year and two subsequent Fiscal Years.
1. Additional expenditures in the current State Fiscal Year. (Approximate)
\$
2. Savings in the current State Fiscal Year. (Approximate)
\$
3. No fiscal impact exists. This regulation does not affect any federally funded State agency or program.
4. Other. Explain
FISCAL OFFICER SIGNATURE DATE
Docusigned by:  Dan Reagan  10/21/2024
The signature attests that the agency has completed the STD. 399 according to the instructions in SAM sections 6601-6616, and understands he impacts of the proposed rulemaking. State boards, offices, or departments not under an Agency Secretary must have the form signed by the highest ranking official in the organization.
AGENCY SECRETARY DATE
Melissa A. Miller Henson Bryan Cash 10/22/2024 10/17/2024
Finance approval and signature is required when SAM sections 6601-6616 require completion of Fiscal Impact Statement in the STD. 399.
DEPARTMENT OF FINANCE PROGRAM BUDGET MANAGER  DATE

#### **STD 399 ADDENDUM**

# Amend Section 236, Title 14, California Code of Regulations Regarding Importing Live Aquatic Plants and Animals for Research

## **Economic Impact Statement**

#### Overview

The proposed regulatory action will amend Section 236 of Title 14, California Code of Regulations, to allow the importation of live aquatic plants, in addition to animals, by a registered aquaculturist for the purpose of research, including when a disease or pathogen has been detected in the shipment prior to importation. The proposed changes will improve the process to import live aquatic plants and animals for research and development. The regulations will limit the use of importation to closed facilities that prevent release, and with no intent to outplant or offer for sale. The registered aquaculturist will be required to maintain all the aquatic plants or animals identified in the permit in a fully closed system that does not have an outlet into the waters of the state. More details and explanations for calculations and assumptions in select sections of the STD 399 are presented in this addendum below.

#### A. Estimated Private Sector Cost Impacts

Answer: 1. h. None of the above (Explain below)

The Commission anticipates that the proposed regulatory action will have no new costs imposed on businesses or small businesses that operate as aquaculturists and seek to import specimens with non-catastrophic diseases, parasites, or pathogens, since they will only incur the current costs of compliance that aquaculturists seeking to import speciments already face as part of the permitting process. The proposed regulatory action removes a prohibition on the importation of species identified as being infected with non-catastrophic diseases or pathogens to allow the research of diseased aquatic plants, in addition to animals, under safe and prescribed conditions.

Under current regulations, applicants for an importation license incur costs for required diagnostic and testing services for pathogens; costs vary from approximately \$4,000 to \$10,000, depending on the need for repeated testing, with a median cost of \$8,000. Currently, most aquaculturists qualify as small businesses, but the sector is not limited to small businesses in terms of who may enter the market. In 2024 there are approximately 130 registered aquaculture facilities in the state; in some cases, multiple facilities are operated by the same company.

Only a fraction of the companies may conduct the kind of research being contemplated for approval under the proposed regulatory action. However, this testing cost is the same cost that all other importers face when importing a species into the state and does not represent a new cost created or imposed by these regulations. Without a regulation change, the opportunity to allow research of diseased aquatic plants under safe and prescribed conditions will not exist.

# **Fiscal Impact Statement**

#### A. Fiscal Effect on Local Government

Answer: 5. No fiscal impact.

The Commission anticipates that the proposed regulatory action will have no fiscal effect on any local government entity or program.

#### **B. Fiscal Effect on State Government**

Answer: 3. No fiscal impact.

The Commission anticipates that the proposed regulatory action will have no fiscal effect on state government. The Commission has determined that the proposed regulatory action will not affect the Commission's or California Department of Fish and Wildlife's existing level of staff effort involved in monitoring the importation permitting program or law enforcement activities, nor would this action increase or decrease license or other fee revenue. Additionally, no other state agencies or programs would be affected by this regulatory action.

# C. Fiscal Effect on Federal Funding of State Programs

Answer: 3. No fiscal impact.

The proposed regulatory action will not have a fiscal effect on federal funding of state programs.