### 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) 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 facilities. 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

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.