

**State of California
Office of Administrative Law**

In re:
Department of Public Health

Regulatory Action:

**Title 17, California Code of
Regulations**

**Adopt sections: 7700, 7702, 7703,
7706.1, 7707.1,
7707.2, 7712.1,
7712.5, 7727**

**Amend sections: 7706, 7707, 7708,
7709, 7712, 7713,
7714, 7725, 7730,
7731, 7732, 7738,
7739**

**Repeal sections: 7710, 7711, 7720,
7733, 7740, 7741,
7742, 7743, 7744,
7745, 7746, 7747,
7748, 7749, 7750,
7751, 7753, 7754,
7755, 7756, 7757,
7758, 7759, 7760,
7761, 7762**

**DECISION OF DISAPPROVAL OF
REGULATORY ACTION**

Government Code Section 11349.3

OAL Matter Number: 2026-0114-01

OAL Matter Type: Regular (S)

SUMMARY OF REGULATORY ACTION

This regulatory action by the California Department of Public Health (Department) proposed to adopt and amend regulations to update existing shellfish sanitation standards including adoption of the 2023 National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

On January 14, 2026, the Department submitted the above-referenced regulatory action to the Office of Administrative Law (OAL) for review. On February 27, 2026, OAL notified the Department that OAL disapproved the

proposed regulatory action pursuant to the Administrative Procedure Act (APA). This Decision of Disapproval of Regulatory Action explains the reasons for OAL's action.

DECISION

OAL disapproved the action because the proposed regulatory changes failed to comply with the clarity standard of Government Code section 11349.1, subdivision (a)(3).

DISCUSSION

The Department's regulatory action must satisfy requirements established by the part of the APA that governs rulemaking by a state agency. Any regulation adopted, amended, or repealed by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.) No exemption applies to the present regulatory action under review.

Before any regulation subject to the APA may become effective, the regulation is reviewed by OAL for compliance with the procedural requirements of the APA and the standards for administrative regulations in Government Code section 11349.1. Generally, to satisfy the APA standards, a regulation must be legally valid, supported by an adequate record, and easy to understand. In this review, OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency regarding the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on regulations before they become effective.

1. Clarity Standard

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to persons who must comply with the regulations. (Gov. Code, sec. 11340, subd. (b).) Government Code section 11349.1, subdivision (a)(3), requires that OAL review all regulations for

compliance with the clarity standard. Government Code section 11349, subdivision (c), defines “clarity” to mean “written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.”

The “clarity” standard is further defined in section 16 of title 1 of the California Code of Regulations (CCR), which provides:

In examining a regulation for compliance with the “clarity” requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:

- (a) A regulation shall be presumed not to comply with the “clarity” standard if any of the following conditions exists:
 - (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
 - (2) the language of the regulation conflicts with the agency’s description of the effect of the regulation; or
 - (3) ...
 - (4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
 - (5) the regulation presents information in a format that is not readily understandable by persons “directly affected;” or
 - (6) the regulation does not use citation styles which clearly identify published material cited in the regulation.
- (b) Persons shall be presumed to be “directly affected” if they:
 - (1) are legally required to comply with the regulation; or
 - (2) are legally required to enforce the regulation; or
 - (3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or
 - (4) incur from the enforcement of the regulation a detriment that is not common to the public in general.

The following provisions in the Department’s proposed regulatory action do not satisfy the clarity standard.

1.1 Proposed Subsection (a) of Section 7707.2

Proposed subsection (a) of section 7707.2 reads:

When the Department re-inspects because of a violation, a dealer must submit a fee of one hundred fifty-six dollars (\$156) per hour to the Department for each re-inspection of the same shellfish facility that occurs within a 12-month period.

Two provisions within proposed subsection (a) are unclear.

First, proposed subsection (a) establishes that reinspection occurs “because of a violation”; however, the proposed regulation does not state what constitutes a “violation” that would trigger or mandate a reinspection. One commenter echoed this clarity concern, stating:

Provide language to clarify what the threshold is for re-inspection? Would it be required when corrective actions not taken? When a recall exists?

Without further information, this language can reasonably and logically be interpreted to have more than one meaning and presents information in a format that is not readily understandable by persons “directly affected.” (Cal. Code Regs., tit. 1, sec. 16, subs. (a)(1) and (a)(5).)

Additionally, this provision is unclear because it conflicts with the agency’s description of the effect of the regulation. Proposed subsection (a) only states reinspection occurs “because of a violation”, however the Department explains in the Initial Statement of Reasons:

Re-inspections can happen when conditions and practices observed in the facility result in the production of a product that was unwholesome or that presented a threat to consumer health or safety. A re-inspection is a specific activity to ensure egregious sanitation violations were corrected from the initial inspection.

...

An average of two shellfish dealers have required a re-inspection within a 12-month period to ensure that operations were conducted in a sanitary manner.

In a response to a comment, the Department further explains in the Final Statement of Reasons:

A dealer would be reinspected within the same certification period if they failed to correct critical violations where shellfish was observed to be adulterated, misbranded or falsely advertised.

The stated clarifications in the rulemaking record appear to be the standard by which reinspection would occur. However, this standard does not appear in the regulation itself. Therefore, this provision is unclear because it conflicts with the agency's description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(2).)

Second, proposed subsection (a) establishes a reinspection fee of "one hundred fifty-six dollars (\$156) per hour"; however, the regulation does not specify how the \$156 per hour fee is applied. Without further information, this language presents information in a format that is not readily understandable by persons "directly affected." (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(5).)

Additionally, this provision is unclear because it conflicts with the agency's description of the effect of the regulation. Proposed subsection (a) only states the reinspection fee is "one hundred fifty-six dollars (\$156) per hour", however the Department explains in the Initial Statement of Reasons:

The average re-inspection time was approximately six hours, which **included an on-site inspection, report, and travel time.** [Emphasis added.]

In a response to a comment, the Department explains in the Final Statement of Reasons:

Per Departmental policy, **the hourly time starts from the closest point of travel from the nearest district office or hotel accommodations in remote locations.** As with our Processed Food Registration program, **the fee covers travel, inspection, and report writing.** [Emphasis added.]

These relevant details regarding how the hourly fee is applied, including timeframes and covered activities, are not specified in the regulations. Therefore, this provision is unclear because it conflicts with the agency's description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(2).)

1.2 Proposed Subsections (b) and (c) of Section 7712, Proposed Subsections (a) and (b) of Section 7712.1, and Proposed Subsections (b) and (c) of Section 7712.5

Proposed subsections (b) and (c) of section 7712 read:

(b) Each Shellfish Growing Area Certificate applicant must **provide all requested information** on the **revok** to be approved by the Department.

(c) **At a minimum**, each applicant must provide the following to the Department **in writing or electronically** to apply for a Shellfish Growing Area Certificate:

[Emphasis added.]

Proposed subsections (a) and (b) of section 7712.1 read:

(a) Each Shellfish Relay Certificate applicant must **provide all requested information** on the application to be approved by the Department.

(b) **At a minimum**, each applicant must provide the following to the Department **in writing or electronically** to apply for a Shellfish Relay Certificate:

[Emphasis added.]

Proposed subsections (b) and (c) of section 7712.5 read:

(b) Each Shellfish Handling and Marketing Certificate applicant must **provide all requested information** on the application to be approved by the Department.

(c) **At a minimum**, each applicant must provide the following to the Department **in writing or electronically** to apply for a Shellfish Handling and Marketing Certificate:

[Emphasis added.]

These proposed subsections are unclear for two reasons.

First, the proposed subsections are unclear because they can be reasonably and logically interpreted to have more than one meaning and they present information in a format that is not readily understandable by persons “directly affected.” (Cal. Code Regs., tit. 1, sec. 16, subs. (a)(1) and (a)(5).) As written, it is unclear whether an applicant “must provide all requested information on the application to be approved by the Department” as specified in the first paragraph or must provide only the outlined “minimum” information as specified in the second paragraph. Additionally, it is unclear whether the outlined “minimum” information is the totality of information required on the application.

Second, the proposed subsections are unclear because they conflict with the agency’s description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(2).) The proposed subsections state the information must be provided “to the Department in writing or electronically.” In the Initial Statement of Reasons, for each respective proposed subsection the Department explains:

The applicant needs to provide the following information to the Department in writing or electronically (online application) because verbal conveyance of information can lead to misunderstandings. Firms and the Department are better protected when critical information is submitted in writing or electronically (online application).

While the regulation allows for submission of information “electronically”, it is not limited to submission via an “online application” as suggested in the Initial Statement of Reasons.

Lastly, the term “revok” in proposed subsection (b) of section 7712 is undefined, and therefore uses language incorrectly, and is not readily understandable to those “directly affected.” (Cal. Code Regs., tit. 1, sec. 16, subs. (a)(4) and (a)(5).)

1.3 Proposed Subsection (c)(1) of Section 7712 and Proposed Subsection (c)(1) of Section 7712.5

Proposed subsection (c)(1) of section 7712 reads:

(c) **At a minimum**, each applicant must provide the following to the Department in writing or electronically to apply for a Shellfish Growing Area Certificate:

(1) **Type of application.**

[Emphasis added.]

Proposed subsection (c)(1) of section 7712 reads:

(c) **At a minimum**, each applicant must provide the following to the Department in writing or electronically to apply for a Shellfish Handling and Marketing Certificate:

(1) **Type of application.**

[Emphasis added.]

These proposed subsections are unclear for two reasons.

First, the phrase “at a minimum” makes the regulation unclear because it can be reasonably and logically interpreted to have more than one meaning. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(1).) As written, it is unclear whether the phrase “at a minimum” is permissive to the applicant or whether the Department may require additional information beyond that listed in the regulation.

Second, the phrase “type of application” makes the regulations unclear because it can be reasonably and logically interpreted to have more than one meaning and it conflicts with the agency’s description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, subs. (a)(1) and (a)(2).) As written, it is unclear what “type of application” refers to. However, in the Initial Statement of Reasons, the Department explains:

For subsection (c)(1), the type of application (**new, renewal, or ownership change**) is needed so the Department can distinguish how to handle the application. [Emphasis added.]

These specific types of applications are not identified or otherwise addressed in the regulations.

1.4 Proposed Subsection (a)(2)(A) of Section 7739

Proposed subsection (a)(2)(A) of section 7739 reads:

(a) A validation study of land-based wet storage or depuration systems must be required, in accordance with NSSP Guide Chapter VII .04 (C)(2)(b) and (C)(3)(a), under either of the following conditions:

(1) ...

(2) Upon modifications to the previously permitted wet storage or depuration system. Modifications include, but are not limited to, any of the following:

(A) Equipment changes; or

Proposed subsection (a)(2)(A) is unclear because it can be reasonably and logically interpreted to have more than one meaning and it conflicts with the agency's description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, subs. (a)(1) and (a)(2).) The phrase "equipment changes" is vague, making it unclear what types of equipment changes would trigger validation of a wet storage or depuration system. One commenter echoed this clarity concern, stating:

What modifications to the system justify revalidation? Not specifying the types of activities that require new validation creates uncertainty for shellfish growers.

In response to the comment, the Department explains in the Final Statement of Reasons:

It is for new systems or existing systems that undergo a major change that could affect meeting the critical limits identified in the Hazard Analysis Critical Control Points (HACCP) plan. The activities that would trigger revalidation of an existing wet storage system are including, but not limited to:

- Adding a holding tank to increase the amount of shellstock in the system
- Changing the make, model, and capacity the ultraviolet disinfection system
- Adding or removing pumps, tanks, filters, which change the functionality of the system that was present during the initial validation study
- Adding another system/unit to the facility.

These equipment changes that trigger revalidation are not specified in regulation.

1.5 Proposed Section Title and Subsection (d) of Section 7707.1

The proposed section title and subsection (d) of section 7707.1 read:

§7707.1 Fees for Shellfish Handling and Marketing Certificate and Wet Storage Permit Certificate

(d) The fees for the Shellfish Handling and Marketing certificate and the wet storage permit certificate are adjusted annually pursuant to Health and Safety Code Section 100425.

The proposed section title and subsection (d) of section 7707.1 are unclear because they can be reasonably and logically interpreted to have more than one meaning and they present information in a format that is not readily understandable by persons “directly affected.” (Cal. Code Regs., tit. 1, sec. 16, subs. (a)(1) and (a)(5).) The term “wet storage permit certificate” is used within the proposed section title and subsection (d) of proposed section 7707.1. However, proposed subsection (c) of section 7707.1 and proposed section 7739 refer to a “wet storage permit.” As written, the competing terms make it unclear if these are the same permits or two different types of permits.

1.6 Proposed Subsection (b) of Section 7707

Proposed subsection (b) of section 7707 reads:

A dealer must have at least one person trained or experienced pursuant to Title 21, Code of Federal Regulations, Part 123.10, Fish and Fishery Products.

Proposed subsection (b) is unclear because the regulation does not use a citation style that clearly identifies published material. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(6).) It is unclear whether the Department is incorporating by reference a specific version of the Title 21, Code of Federal Regulations, Part 123.10, Fish and Fishery Products, and whether the Department is seeking to require a dealer to have at least one person trained or experienced pursuant to **Section** 123.10, "Training," or pursuant to **Part** 123, "Fish and Fishery Products," which contains additional training and experience requirements beyond those contained in section 123.10.

For the reasons discussed above, the proposed regulatory changes failed to comply with the clarity standard of the APA.

CONCLUSION

For the foregoing reasons, OAL disapproved the above-referenced regulatory action. Pursuant to Government Code section 11349.4, subdivision (a), the Department may resubmit revised regulations within 120 days of its receipt of this Decision of Disapproval of Regulatory Action. A copy of this Decision will be emailed to the Department on the date indicated below.

The Department must make any substantive regulatory text changes, which are sufficiently related to the originally noticed text, available for public comment for at least 15 days pursuant to subdivision (c) of Government Code section 11346.8 and section 44 of title 1 of the CCR. Any comments containing objections or recommendations must be summarized and responded to in the Final Statement of Reasons. The Department must resolve all issues raised in this Decision of Disapproval of Regulatory Action prior to OAL approving a resubmittal.

Date: March 6, 2026

/s/

Jason W. Falina
Attorney

For: Kenneth J. Pogue
Director

Original: Dr. Erica Pan, Director
Copy: David Martin