

Title 17. Public Health
Division 1. State Department of Health Services
Chapter 5. Sanitation (Environmental)
Subchapter 1. Engineering (Sanitary)
Group 13. Eviscerated Crab

ADOPT
Group 13. Eviscerated Crab

Adopt Section 8056 to read as follows:

§ 8056. Applicability.

The eviscerated crab program regulations apply to a processor who receives, holds, or eviscerates Dungeness crab or rock crab caught in areas subject to a Department Evisceration Order for commercial purposes in California.

Note: Authority cited: Sections 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 108320, Health and Safety Code.

Adopt Section 8057 to read as follows:

§ 8057. Registration and Fees for Eviscerated Crab.

A processor who receives, holds, or eviscerates Dungeness crab or rock crab under a Department Evisceration Order must:

- (a) Possess a valid processed food registration with the Department, renew annually, and pay applicable nonrefundable fees pursuant to Health and Safety Code, Division 104, Part 5, Chapter 5, Article 2 (commencing with section 110460); and
- (b) Possess a valid crab evisceration registration with the Department and renew annually pursuant to section 8061; and
- (c) Pay fees to the Department for initial review and each time the Hazard Analysis Critical Control Point plan is modified pursuant to section 8063. Pay fees to the Department pursuant to Health and Safety Code section 111224.6 for initial review and each time the Hazard Analysis Critical Control Point plan is modified pursuant to section 8063.

Note: Authority cited: Sections 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 108320, Health and Safety Code.

Adopt Section 8058 to read as follows:

§ 8058. Definitions.

For the purposes of the eviscerated crab program, the following definitions apply:

“Action level” means the maximum concentration of a contaminant that cannot be exceeded, as established by the Food and Drug Administration for health hazards posed by toxic substances in food products.

“Approved processor” means a person who has received a registration from the Department to receive, hold, or eviscerate Dungeness crab or rock crab for human consumption under a Department Evisceration Order.

“Biotoxin management areas” means the areas identified for purposes of biotoxin control in the California commercial Dungeness crab and rock crab fishery.

“Commercial fisher” has the same meaning as “Commercial Fisherman” in Fish and Game Code section 8040.

“Crab” means only Dungeness crab or rock crab species.

“Crab sample set” means all whole crab collected during a sample gathering event from a sample site for testing.

“Department Evisceration Order” means an order issued by CDPH authorizing evisceration of Dungeness crab or rock crab harvested from specific biotoxin management areas when the conditions of HSC 111224.5 are met.

“Harvest location” means a section of waters of California or the Pacific Ocean off of California delineated by the Division of Fish and Game for crab traceability purposes and includes all coastal waters, intertidal areas, rivers and ports over which California has jurisdiction, and the Pacific Ocean off of California.

“Landing” means to begin transfer of crab, offloading crab, or to offload crab from any vessel, with all crab aboard the vessel counted as part of the landing once transfer or offloading of crab begins.

“Lot coding” means an identification system assigned by an approved processor to a specific quantity of crab produced during a period of time.

“Sample site” means a location determined collaboratively by the California Department of Fish and Wildlife, Office of Environmental Health Hazard Assessment, and the California Department of Public Health for Dungeness crab or rock crab collection for domoic acid testing.

Note: Authority cited: Sections 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 112165, Health and Safety Code.

Adopt Section 8059 to read as follows:

§ 8059. Crab Testing.

(a) A crab sample set for Dungeness crab is six Dungeness crab. A crab sample set for rock crab is six rock crab.

- (b) Domoic acid testing must be conducted by a laboratory certified for domoic acid testing that is approved by the Department.
- (c) Domoic acid action levels for Dungeness crab and rock crab are the following:
 - (1) Greater than 30 parts per million in viscera is adulterated and fails.
 - (2) Equal to or greater than 20 parts per million in meat is adulterated and fails.
- (d) Each crab must be tested individually for domoic acid.
- (e) Crab viscera samples will be tested first.
 - (1) All six viscera samples in a crab sample set must pass the viscera action level for the sample site to pass.
 - (2) If any viscera sample fails the viscera action level, meat samples will also be tested.
 - (A) If the meat sample fails the meat action level, the Department will consult with the Office of Environmental Health Hazard Assessment to determine if the crab is likely to pose a human health risk from high levels of domoic acid.
 - (B) If the meat sample passes the meat action level, the Department will consult with the Office of Environmental Health Hazard Assessment to determine if the crab is likely to pose a human health risk from high levels of domoic acid.
- (f) If a biotoxin management area is closed by the California Department of Fish and Wildlife, crab may not be donated, given away, sold in whole or in-part, or eviscerated starting from 12:01 a.m. on the harvest date of the affected crab sample set.
- (g) If a biotoxin management area is under a Department Evisceration Order, crab must be eviscerated starting from 12:01 a.m. on the harvest date of the affected crab sample set.
- (h) To rescind a Department Evisceration Order, all crab from two consecutive crab sample sets, at least seven days apart, taken from the same failed sample site, must pass the viscera action level.

Note: Authority cited: Sections 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code.

Adopt Section 8060 to read as follows:

§ 8060. Role and Responsibilities of Approved Processors.

- (a) Approved processors may only receive, hold, or eviscerate crab for evisceration from California Department of Fish and Wildlife licensed commercial fishers,
- (b) All crab caught under a Department Evisceration Order must be sold to an approved processor or transferred to an approved processor.
- (c) Approved processors must identify on the landing receipt that any crab received for evisceration were taken from an area authorized by the Department for evisceration.

Note: Authority cited: Sections 111224.5, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code. Title 21, Chapters 117 and 123, Code of Federal Regulations.

Adopt Section 8061 to read as follows:

§ 8061. Application for Evisceration Registration.

- (a) A separate evisceration registration is required for each place of evisceration.
- (b) New or renewal applicants for evisceration registration must provide at a minimum all information on the Department application and must include all documentation as follows:
 - (1) Type of applicant.
 - (2) Species of crab to be eviscerated.
 - (3) Type of activity.
 - (4) A copy of the Hazard Analysis Critical Control Point Plan pursuant to section 8063.
 - (5) A copy of the Lot Coding System pursuant to section 8065.
 - (6) A copy of the Written Recall Procedures pursuant to section 8064.
 - (7) Submit the Hazard Analysis Critical Control Point review fee for initial review and each time the Hazard Analysis Critical Control Point plan is modified.
 - (8) Signature of owner, printed name, and title of owner, and date application signed, under penalty of perjury that the information included with the application and all attachments are true, correct, and complete to the best of their knowledge.
- (c) The Department may close or deny an application if incomplete.

Note: Authority cited: Sections 110460, 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code.

Adopt Section 8062 to read as follows:

§ 8062. Validity, Renewal, Revocation, and Suspension of Evisceration Registration.

- (a) The evisceration registration issued under this part is valid for one calendar year from the date issued.
- (b) A renewal application must be submitted prior to the expiration date.
- (c) The Department may revoke or suspend an evisceration registration for noncompliance with applicable laws and regulations.
- (d) The evisceration registration is not transferable.

Note: Authority cited: Sections 110460, 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code.

Adopt Section 8063 to read as follows:

§ 8063. Hazard Analysis Critical Control Point Plan.

The approved processor must have and implement a Hazard Analysis Critical Control Point plan, which has been reviewed and approved by the Department, for every crab or crab product harvested from an area under a Department Evisceration Order. The content, at a minimum, must include all of the following:

- (a) Source control.
- (b) Storage control.
- (c) Evisceration control.
- (d) Allergen control.
- (e) Lot Coding control.
- (f) Other food safety hazards that are reasonably likely to occur.

Note: Authority cited: Sections 110460, 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code.

Adopt Section 8064 to read as follows:

§ 8064. Written Recall Procedures.

The approved processor must have and implement Written Recall Procedures that must, at a minimum, contain all of the following:

- (a) Create, implement, and maintain procedures that describe how to trace affected product back to the supplier(s) and forward through distribution.
- (b) Maintain accurate and legible transaction records that are sufficient to trace affected product back to the supplier(s) and forward through distribution.
- (c) Require timely notification to the Department of a situation requiring a recall, timely notification to consignee who received the affected product, and effective removal or correction of the affected product.

Note: Authority cited: Sections 110460, 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code. Title 21, Chapters 117 and 123, Code of Federal Regulations.

Adopt Section 8065 to read as follows:

§ 8065. Lot Coding System and Labeling

(a) The approved processor must have and implement a Lot Coding System. The system, at a minimum, must allow traceability of all of the following:

- (1) Product identity
- (2) Supplier information.

- (3) Harvest location.
- (4) Date received by approved processor.
- (5) Date of production.
- (6) Species and quantity – incoming and outbound.
- (7) Distribution information.
- (b) Eviscerated crab placed in bulk packaging for further processing, must be labeled in the following manner:
 - (1) Identify the lot code; and
 - (2) Common or usual name of the product; and
 - (3) The name and place of approved processor; and
 - (4) Weight or quantity of contents.
- (c) Eviscerated crab placed in retail packing must be labeled in the following manner:
 - (1) Identify the lot code on the principal display or information panel; and
 - (2) Comply with 21 CFR 101 pursuant to Health and Safety Code section 110100.

Note: Authority cited: Sections 110100, 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code. Title 21, Chapters 117 and 123, Code of Federal Regulations.

Adopt Section 8066 to read as follows:

§ 8066. Recordkeeping.

The approved processor must maintain all of the following documentation and have them immediately available for inspection by the Department during all reasonable hours:

- (a) Supplier information.
- (b) Harvest location.
- (c) Date received by approved processor.
- (d) Production records.
- (e) Species and quantity.
- (f) Distribution information.
- (g) Hazard Analysis Critical Control Point records.

Note: Authority cited: Sections 110460, 111224.6, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code. Title 21, Chapters 117 and 123, Code of Federal Regulations.

Adopt Section 8067 to read as follows:

§ 8067. Prohibition.

- (a) It is unlawful for a person to give away, donate, sell, or offer for sale uneviscerated crab harvested from an area under a Department Evisceration Order except to an approved processor.
- (b) It is unlawful for an approved processor to receive, hold, or eviscerate crab from an area where a meat sample was found with domoic acid equal to or greater than the meat action level.
- (c) It is unlawful for any person to forge, falsify, fail to retain, fail to obtain, or fail to disclose records pursuant to section 8066. The Department may take enforcement action against a person who engages in falsification including, but not limited to, suspension or revocation of an evisceration registration.
- (d) It is unlawful for any person to make a false and misleading statement or representation, or fail to disclose a fact required to be disclosed, on a registration application or document. False and misleading means untruthful.
- (e) It is unlawful for any person to alter any registration certificate or registration document.
- (f) It is unlawful for any person to falsify any document.

Note: Authority cited: Sections 111825-111855, 111860, 111890, 111224.5, 110065, and 131200, Health and Safety Code.

Reference: Section 110460, 110466, 110474, Health and Safety Code.