

OFFICE OF THE SECRETARY OF STATE
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Attachment 5

ARCHIVES DIVISION
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503-373-0701

NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 603
DEPARTMENT OF AGRICULTURE

FILED

08/13/2021 9:57 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Crab harvested outside Oregon in an area that would be a biotoxin management zone.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/24/2021 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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635 Capitol St NE
Salem, OR 97301

Filed By:
Alex Thomas
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 09/22/2021

TIME: 1:00 PM

OFFICER: Karel Smit

ADDRESS: Oregon Department of
Agriculture

635 Capitol St NE

Salem,, OR 97301

SPECIAL INSTRUCTIONS:

Virtual

NEED FOR THE RULE(S):

Domoic acid is a natural toxin that can accumulate in certain shellfish and fish species, including Dungeness crab, and cause serious illness in consumers. Amnesic shellfish poisoning from domoic acid is characterized by gastrointestinal symptoms, and in severe cases, neurological symptoms, memory loss, respiratory difficulty, and coma. Because amnesic shellfish poisoning caused by the consumption of Dungeness crab containing unsafe levels of domoic acid can cause serious illness, it is necessary for the Department of Agriculture to require that crab that may contain unsafe levels of domoic acid in the viscera is processed in a manner that removes unsafe levels of domoic acid. Making this a permanent rule establishes that Dungeness crab that (1) contains viscera, and (2) was harvested outside Oregon in an area in which crab viscera samples showed domoic acid levels of 30 ppm or higher may not be sold, offered for sale, delivered, or donated in Oregon unless the crab is processed to remove the viscera in accordance with this rule.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, 2019 Revision. Available at:
<https://www.fda.gov/media/143238/download>

FISCAL AND ECONOMIC IMPACT:

Minimal. The proposed amendments will not change the regulatory framework that ODA applies to shellfish; there will not be additional regulatory costs. Also, industry and stakeholders will not be fiscally or economically impacted because the National Shellfish Sanitation Program: Guide for the Control of Molluscan Shellfish 2019 Revision is already the industry standard.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s): Minimal

(2) Effect on small businesses: (a) estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

A) Minimal B) Minimal C) Minimal

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses are involved and allowed to participate in the development of the National Shellfish Sanitation Program (NSSP) during the biennial Interstate Shellfish Sanitation Conference (ISSC).

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

There are no substantial changes to ODA regulations. The proposed permanent adoption to the existing rule establishes that Dungeness crab that (1) contains viscera, and (2) was harvested outside Oregon in an area in which crab viscera samples showed domoic acid levels of 30 ppm or higher may not be sold, offered for sale, delivered, or donated in Oregon unless the crab is processed to remove the viscera in accordance with this rule. The proposed amendment also reflects federal standards and practices that are similar to regulations that are currently enforced in Oregon.

ADOPT: 603-025-0425

RULE SUMMARY: Domoic acid is a natural toxin that can accumulate in certain shellfish and fish species, including Dungeness crab, and cause serious illness in consumers. Amnesic shellfish poisoning from domoic acid is characterized by gastrointestinal symptoms, and in severe cases, neurological symptoms, memory loss, respiratory difficulty, and coma.

Because amnesic shellfish poisoning caused by the consumption of Dungeness crab containing unsafe levels of domoic acid can cause serious illness, it is necessary for the Department of Agriculture to require that crab that may contain unsafe levels of domoic acid in the viscera is processed in a manner that removes unsafe levels of domoic acid.

Making this a permanent rule establishes that Dungeness crab that (1) contains viscera, and (2) was harvested outside Oregon in an area in which crab viscera samples showed domoic acid levels of 30 ppm or higher may not be sold, offered for sale, delivered, or donated in Oregon unless the crab is processed to remove the viscera in accordance with this rule.

CHANGES TO RULE:

603-025-0425

Crab Harvested Outside Oregon in an Area that Would Be a Biotxin Management Zone, if in Oregon

(1) Application. This rule applies only to Dungeness crab (Cancer magister or Metacarcinus magister) harvested and sold for commercial purposes that:

(a) Contains viscera, whole or in part;

(b) Is not harvested in waters of this state or the Pacific Ocean off Oregon;

(c) Is harvested from an area in which crab viscera samples that were tested under the authority of the responsible state agency showed domoic acid levels of 30 ppm or higher; and

(d) Is sold into, or otherwise enters, Oregon.

(2) Definitions. The definitions in OAR 603-025-0410 apply to this rule, except for the definition of "crab" in OAR 603-025-0410(2)(c).

(3) Prohibitions.

(a) It is prohibited to sell, offer for sale, deliver or donate crab described in section (1) of this rule unless:

(A) The crab is conveyed or sold to a food processing establishment licensed by ODA or to a licensed food processor that eviscerates and processes crab consistent with subsection (3)(d); or

(B) The crab is conveyed or sold to a wholesaler that in turn sells all crab subject to these rules to a food processor that is licensed by ODA or to a licensed processor.

(b) In no case may uneviscerated crab be conveyed, sold or donated to retailers or directly to consumers unless it is processed as described in subsection (3)(c).

(c) Food processors or wholesalers are prohibited from selling or offering for sale to retailers or to consumers crab as described in this section unless:

(A) The licensed processor conducts its activities consistent with a seafood HACCP plan; and

(B) The crab is eviscerated.

(d) If section (1) of this rule accurately describes any of the landed crab in a landing from a fishing vessel, the entire landing shall be subject to the requirements of this section. Landings for which the harvest location is unspecified shall be subject to the requirements of this section. Failure of a producer or wholesaler to notify processors that crab originated from an area in which domoic acid levels in viscera were 30 ppm or higher and therefore must be processed consistent with this section before it is donated, held, offered for sale or sold to consumers will be considered a violation of ORS 616.215(1).

(4) Penalties. Whenever it is found that any crab described in this rule is sold, offered for sale, or donated to any person in a manner that is inconsistent with this rule, the crab is considered adulterated food, and the holding, or offering for sale of crab is prohibited as provided in ORS 616.215(1). If any person violates this rule, ODA may proceed with any lawful remedy including:

(a) Seeking the district attorney to institute proceedings in the proper courts to be prosecuted in the manner required by law;

(b) Enjoining violations of law in a summary proceeding;

(c) Embargo, seizure or detention consistent with the provisions of ORS 561.605 - 630;

(d) Civil penalties up to \$10,000 for each violation as provided in ORS 616.997.

Statutory/Other Authority: ORS 616.215, ORS 616.225, ORS 616.235, ORS 561.190

Statutes/Other Implemented: ORS 616.215, ORS 616.235