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August 11, 2016

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RE: Domoic Acid Issue in California (NSGLC-16-04-05)

This product was prepared by the National Sea Grant Law Center under award number NA14OAR4170065 from the National Oceanic and Atmospheric Administration, U.S. Department of Commerce. The statements, findings, conclusions, and recommendations are those of the author and do not necessarily reflect the views of NOAA or the U.S. Department of Commerce.

Dear Carrie,

Thank you for submitting an advisory request to the National Sea Grant Law Center regarding your legal and policy questions related to the fishery closures triggered by elevated levels of domoic acid in crab samples during the 2015-2016 fishing season. This memo summarizes the result of our research into the four questions you presented in your June 20, 2016 email.

Is the FDA Guidance related to domoic acid in crab (and other species) mandatory or not?

The Federal Food, Drug, and Cosmetic Act (FFDCA) prohibits the “delivery or introduction for delivery into interstate commerce” of any food that is adulterated.¹ Pursuant to the FFDCA, a food is adulterated “if it bears or contains any poisonous or deleterious substance which may render it injurious to health.”² The FFDCA provides no threshold level of contamination to guide a decision regarding whether a food is in fact adulterated.

Under the FFDCA, the U.S. Food and Drug Administration (FDA) publishes actions levels for determining when a food is considered adulterated. However, the action levels are published as informal agency guidance, not as formal regulations. Agency regulations carry the force of law,

¹ 21 U.S.C. § 331(a).

² *Id.* § 342(a)(1).

meaning they create legally enforceable rights and duties. Guidance is generally considered advisory in nature and therefore carries less weight.

According to the FDA, action levels are “prosecutorial guidelines.”³ Action levels “are not binding on the courts, the public (including food producers) or the agency (including individual FDA employees).⁴ As stated by the U.S. Supreme Court, “[i]n setting an action level, the FDA essentially assures food producers that it ordinarily will not enforce the general adulteration provisions of the [FFDCA] against them if the quantity of the harmful substance in their food is less than the quantity specified by the action level.”⁵

The FDA has established action levels for natural toxins in seafood. A comprehensive list of the existing action levels can be found in Chapter 6 of the FDA’s Fish and Fishery Products Hazards and Controls Guidance (4th ed. 2011).⁶ With respect to domoic acid, the action level is 20 ppm, except in the viscera of Dungeness crab, where the action level is 30 ppm.⁷ These levels were established in the early 1990’s.⁸

Because they are not legally binding, the FDA is not required to adhere to the guidelines. The FDA, for example, may choose to initiate enforcement action if a substance is present in amounts below the action level. The FDA may also refrain from taking enforcement action when action levels are exceeded. Enforcement, therefore, is solely within the discretion of the FDA. The agency has stated, however, that whether the FDA will recommend enforcement in any particular case “will depend on the extent of contamination, the strength of the evidence of adulteration . . . , the risks to health presented by the . . . substance, the amount of food involved, and other factors.”⁹

Although action levels are not legally binding, they remain important statements of FDA policy on the health risks associated with a particular substance. FDA action levels carry significant weight in determining whether a food is adulterated. State health officials give serious consideration to FDA guidance in their decision-making processes. Further, since the FDA retains enforcement discretion, food producers who deviate from agency guidance run the risk of enforcement action.

³ 53 Fed. Reg. 5043 (Feb. 19, 1988).

⁴ *Id.*

⁵ *Young v. CNI*, 476 U.S. 974 (1986).

⁶ Available at

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm> .

⁷ U.S. Food and Drug Administration, Fish and Fishery Products Hazards and Controls Guidance 101 (4th ed. 2011) (*hereinafter* “HACCP Guide”).

⁸ *See* U.S. Food and Drug Administration, Health Hazard Evaluation Board, Center for Food Safety and Applied Nutrition, Recommendation # 2734, Dec. 9, 1991 (20 ppm) and Recommendation # 2937 October 5, 1993. (30 ppm). These documents are not publically available. The NSGLC submitted a Freedom of Information request to the FDA on June 27, 2016.

⁹ 53 Fed. Reg. 5,043 (Feb. 19, 1988).

Q2: Do all states interpret and implement the guidance in the same way such that the sale of “adulterated product” is prohibited once domoic acid levels reach the action level?

State law in California, Oregon, and Washington mirrors the FFDCFA and prohibits the sale, delivery, and receipt of adulterated food in commerce.¹⁰ Food is considered adulterated in all three states if it “bears or contains any poisonous or deleterious substance which may render it injurious to health.”¹¹ Because state law closely parallels federal law, food that is deemed adulterated under federal law would also be deemed adulterated under state law. The sale of shellfish, crab, and other seafood containing domoic acid in exceedance of FDA action levels is therefore prohibited in all three states.

The closure of a fishery also operates to prevent the sale of crab, regardless of whether FDA action levels are exceeded in individual crabs (and therefore adulterated). State officials in California, Oregon, and Washington responded to the 2015 harmful algal bloom in similar fashion. Throughout the summer and fall of 2015, the state departments of fish and wildlife enacted a number of emergency regulations to close or delay the opening of recreational and commercial crab fisheries due to high levels of domoic acid. The fishery closures were triggered by test results from the state departments of health indicating that domoic acid levels in crabs exceeded federal and state action levels.

California’s Dungeness Crab and Rock Crab Emergency Closure regulations prohibited the take and possession of all Dungeness and rock crab from any ocean waters north of the Ventura/Santa Barbara county line.¹² Oregon’s regulations closing the Dungeness crab fishery stated that it was unlawful to take, land, or possess Dungeness crab for commercial purposes taken “from a health closure area closed for biotoxins.”¹³ Washington’s emergency rules closing the commercial Dungeness crab fishery made it unlawful to possess, transport, or deliver Dungeness crab within closed waters.¹⁴ If it is unlawful to possess Dungeness crab for commercial purposes, there are no crab legally available to sell.

Even if possession and sale were legal, seafood processors are unlikely to accept seafood harvested from closed waters. FDA regulations require seafood processors to develop and implement a written Hazard Analysis Critical Control Point (HACCP) plan.¹⁵ HACCP plans must list the food safety hazards that are reasonably likely to occur, including natural toxins, and the strategies the processors will use to control the hazards.¹⁶ The FDA’s *Fish and Fishery Products Hazards and Control Guidance* (“HACCP Guide”) provides guidance and recommendations to assist seafood processors in the development of seafood HACCP plans.

The HACCP Guide’s control strategy example for natural toxins encourages primary processors to establish the following critical limit in their HACCP plans: “No fish may be received that has been

¹⁰ See CAL. HEALTH & SAFETY CODE § 110620; ORE. REV. STAT. ANN. § 616.215; WASH. REV. CODE ANN. § 69.05.040.

¹¹ See CAL. HEALTH AND SAFETY CODE § 110545; ORE. REV. STAT. ANN. § 616.235(1)(a); WASH. REV. CODE ANN. § 69.04.201(1).

¹² California Dept. of Fish and Wildlife, Notice of Emergency Regulatory Action (Nov. 6, 2015).

¹³ Oregon Dept. of Fish and Wildlife, Administrative Order No. DFW 156-2015, Oregon Bulletin (Dec. 2015).

¹⁴ Washington Dept. of Fish and Wildlife, Emergency Rules 15-238 (Aug. 3, 2015).

¹⁵ 21 C.F.R. § 123.6(a).

¹⁶ *Id.* § 123.6(c).

harvested from ... an area that is the subject of a [Amnesic Shellfish Poisoning] consumption advisory.”¹⁷ For each critical limit listed in the HACCP plan, processors must identify corrective action procedures to be taken in the event of a deviation from the critical limit. With respect to natural toxins, the HACCP Guide recommends two corrective actions: (1) reject the lot; and (2) discontinue use of the supplier until evidence is obtained that harvesting practices have changed.¹⁸

FDA guidance for marine biotoxin control in shellfish is similar. The National Shellfish Sanitation Guide (Shellfish Model Ordinance) instructs that state shellfish authorities should classify waters as closed to shellfish harvesting if domoic acid levels rise above 20 ppm.¹⁹ Pursuant to FDA regulations, “[p]rocessors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority.”²⁰ Similar source control regulations do not exist for crab.

The HACCP Guide, like the FDA action levels, does not create any legally enforceable responsibilities. The HACCP Guide acknowledges that processors may select different strategies to control natural toxins. Alternative approaches, however, must comply with all applicable laws and be accepted by the FDA.

Q3: Is it possible to develop warning labels such as those used with other products so that whole crab can continue to be sold to buyers and consumers when domoic acid levels are above the action level?

FDA guidance suggests that warning labels are not a viable option to facilitate the sale of adulterated crab in the marketplace. In a January 1993 memo to state health officials announcing the adjustment of the domoic acid level for Dungeness crab viscera, the Director of the FDA’s Office of Seafood stated that the “FDA will take action on contaminated crabs whether or not the product bears a warning tag or label.”²¹ To prevent consumer exposure to domoic acid, the FDA suggests that states consider two options: (1) close harvest areas or (2) eviscerate contaminated crabs to remove the contaminated viscera.²²

In its 2008 management strategy for domoic acid exposure from Dungeness crab, the State of Washington acknowledged that evisceration of crab is an alternative to harvesting closures.²³ More recently, in an August 5, 2016 memorandum to the California Dungeness crab industry, California suggested commercial harvest might be allowed during a future event if sales were limited to

¹⁷ HACCP Guide, *supra* note 8, at 108.

¹⁸ *Id.*

¹⁹ See National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish 2015 Revision, Section II, Ch. IV @.4 (2015).

²⁰ 21 C.F.R. § 123.28.

²¹ Memorandum from Thomas J. Billy, Director, Office of Seafood, Food and Drug Administration, Department of Health and Human Services, to Heinz Wilms, Director of Division of Federal-State Relations re: Marine Biotoxins in Dungeness Crab (Jan. 14, 1993).

²² *Id.*

²³ Washington State Department of Health et al, Strategy for Preventing Consumer Exposure to Domoic Acid from Dungeness Crab (Nov. 24, 2008).

eviscerated crab.²⁴ Such a policy might allow HACCP-certified processors to accept crab from areas affected by domoic acid, but prohibit the sale of live or whole crab with domoic acid in exceedance of FDA action levels.²⁵

Another common risk reduction tool used by public health agencies that might arise during management discussions regarding domoic acid are seafood consumption advisories. Advisories can be used in combination with or as an alternative to a harvesting ban in some situations. Fish consumption “[a]dvisories fill two different roles: They discourage fishing, and they discourage consumption of fish once caught--providing information that consumers can use to protect themselves.”²⁶ Agencies may rely on advisories in situations where there is insufficient scientific evidence for harvesting bans or enforcement challenges.²⁷ Achieving desired public health goals utilizing fish consumption advisories is challenging, however, as agencies are relying on the public to voluntarily heed their warnings. Public health officials, therefore, may consider harvesting bans to be more protective of public health.

Public health officials in California, Oregon, and Washington have issued consumption advisories during domoic acid events.²⁸ Consumption advisories have no legal effect – they simply provide a warning to consumers. Advisories cannot operate to permit the sale of adulterated product. The issuance of an advisory does not impact the determination of whether a particular product is adulterated. Crab meat or viscera containing domoic acid in exceedance of the action levels would be deemed adulterated and its sale prohibited regardless of whether a consumption advisory was in effect.

Although not explicitly stated, the consumption advisories issued during the 2015-2016 domoic acid event may have been primarily targeted at recreational harvesters and others who might obtain crab through non-commercial channels. FDA guidance directs seafood processors to consider state-issued consumption advisories when developing a HACCP plan and undertaking a hazards analysis.²⁹ If the advisory is based on a state decision that seafood harvested from the area is likely to exceed FDA action levels, seafood processors “must test every lot of fish before accepting it.”³⁰

Q4: Do all states use the same procedure?

Yes, all states follow the similar monitoring and sampling procedures which are based on the Washington Department of Health protocol “Strategy for Preventing Consumer Exposure to Domoic Acid from Dungeness Crab.”³¹ The Washington protocol does not specifically reference the testing

²⁴ Memorandum from California Department of Public Health et al. to California Dungeness Crab Industry re: Domoic Acid Background and Potential Option for Future Events (Aug. 5, 2016).

²⁵ *Id.*

²⁶ Michael Gochfeld, *Fish Advisories: Useful or Difficult to Interpret*, 7 RISK 23, 25 (1996).

²⁷ *Id.*

²⁸ *See, i.e.*, California Department of Public Health, Press Release, CDPH Issues Warning about Dungeness and Rock Crabs Caught in Waters Along the Central and Northern California Coast (Nov. 3, 2015); Oregon Department of Agriculture, New release: Crab advisory issued for domoic acid (Nov. 3, 2015).

²⁹ FDA, HACCP Regulation for Fish and Fishery Products: Questions and Answers, Food Drug Cosm. L. Rep. P. 330,029, 1999 WL 35775638 (Jan. 1, 1999).

³⁰ *Id.*

³¹ California Ocean Science Trust, Frequently Asked Questions: Harmful Algal Blooms and California Fisheries 15 (Aug. 5, 2016). *See also*, Washington State Department of Health, *supra* note 23.

method used. Most states, however, use a high-performance liquid chromatography (HPLC) method. According to FDA's Bad Bug Book, "[t]he most accepted regulatory method for detecting domoic acid in seafood is a reversed-phase HPLC method with ultraviolet (UV) detection."³²

The NSSP Guide for the Control of Molluscan Shellfish 2015 Revision identifies two "approved limited use methods" for domoic acid testing in molluscan shellfish.³³ One is an HPLC method developed by Mark Quilliam.³⁴ The other is Reveal 2.0 ASP, "a lateral flow immunoassay designed for qualitative determination of domoic acid in shellfish at levels of 10 ppm (mg/kg) and above."³⁵ There is also an AOAC approved Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of domoic acid at certain levels in mussels, scallops, and oysters.³⁶ These other non-HPLC methods have not been approved for the detection of domoic acid in crabs or other seafood species.

I hope you have found this information useful. If you have follow-up questions or would like additional information, please let me know. Additionally, I would be happy to work with you to translate this information into other formats that may be more useful to your stakeholders.

Sincerely,



Stephanie Otts

Director

³² Food and Drug Administration, *Bad Bug Book: Handbook of Foodborne Pathogenic Microorganisms and Natural Toxins* 204 (2013).

³³ National Shellfish Sanitation Program, *Guide for the Control of Molluscan Shellfish 2015 Revision*, Section IV, Ch. II @.14(4) (2015).

³⁴ M.A. Quilliam et al, *Rapid Extraction and Cleanup for Liquid Chromatographic Determination of Domoic Acid in Unsalted Seafood*, *JOURNAL OF AOAC INTERNATIONAL*, Vol. 78(2): 543-554 (1995).

³⁵ Reveal 2.0 ASP. Neogen Corporation. Screening Method for Qualitative Determination of Domoic Acid Shellfish. ISSC 2013 Summary of Actions Proposal 13-112.

³⁶ See AOAC Official Method 2006.02. Domoic Acid Toxins in Shellfish. Biosense ASP ELISA). (AOAC International is a "voluntary consensus standards developing organization." When no testing method is identified in regulation, it is FDA policy to utilize in its enforcement program the official methods of analysis of AOAC International. (21 C.F.R. § 2.19).