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The Honorable Jared Huffman  
U. S. House of Representatives  
Washington, D.C. 20515-0502

Dear Representative Huffman:

Thank you for your letter of May 7, 2019, regarding the guidance levels discrepancy in the *Fish and Fishery Products Hazards and Controls Guidance* (The *Guide*) fourth edition, April 2011. We appreciate the opportunity to clarify the action level for domoic acid in the viscera of Dungeness Crab. Where domoic acid is detected in the cooked crab viscera, the Food and Drug Administration (FDA or the Agency) will take action when domoic acid is present at *greater than 30 parts per million* (ppm). As you request, the Agency is taking steps to clarify this as part of an update to the relevant guidance document.

In 1992, FDA published a memorandum indicating that we would take regulatory action on Dungeness Crab in interstate commerce found to contain 20 ppm or more domoic acid in the cooked crab viscera. This decision was based on an evaluation by the FDA's Center for Food Safety and Applied Nutrition Health Hazard Evaluation Board. However, the Health Hazard Evaluation Board reassessed the hazard based on additional data and recommended the Agency adjust the tolerable level of domoic acid in Dungeness crab. In 1993, FDA issued a revision to the prior year's levels which concluded that a greater than 30 ppm level in the viscera of Dungeness Crab would be appropriate for taking regulatory action. This revision provided a clarification on the actionable levels, stating "FDA will take regulatory action on any Dungeness crab in interstate commerce, which is found to be contaminated with greater than 30 ppm domoic acid in the cooked crab viscera."

The *Guide* was first published in 1996, and included in *Chapter 6 – Natural Toxins* that the established guidance levels for domoic acid in the viscera of Dungeness Crab to be "where 30 ppm is permitted." The language remained the same in the second and third editions; however, when the guide was updated from the third to the fourth edition in 2011, a typographical error occurred in *Chapter 6 – Natural Toxins*. As a result of the typographical error, the actionable level went from "30 ppm being permitted" to "the action level is 30 ppm." *Appendix 5 – FDA and EPA Safety Levels in Regulations and Guidance* of the *Guide* identified the correct guidance levels of "30 ppm being permitted" in the Dungeness crab viscera. Accordingly, where domoic acid is detected in the cooked crab viscera, FDA will take action when domoic acid is present at greater than 30 ppm.

FDA is currently updating the *Guide* with *Chapter 6 – Natural Toxins* and *Appendix 5 – FDA and EPA Safety Levels in Regulations and Guidance* being the first sections republished. Through this republication the guidance levels will be stated as "> 30 mg/kg domoic acid (Dungeness crab viscera ONLY)" and consistent in the *Guide*.

Thank you, again, for contacting us regarding this matter. If you have any additional questions, please let us know.

Sincerely,

A handwritten signature in blue ink, appearing to read "Karas Gross". The signature is fluid and cursive, with the first name "Karas" being more prominent and the last name "Gross" following in a similar style.

Karas Gross

Associate Commissioner for  
Legislative Affairs