



MEMORANDUM

DATE: August 5, 2016

TO: California Dungeness Crab Industry

FROM: California Department of Public Health
California Department of Fish and Wildlife
California Office of Environmental Health Hazard Assessment

SUBJECT: Domoic Acid Background and Potential Option for Future Events

Background

Domoic acid is a naturally occurring toxin that is related to a “bloom” of a particular single-celled plant called *Pseudo-nitzschia*. The conditions that support the growth of *Pseudo-nitzschia* are impossible to predict, but tend to be more common in the warmer months of the year. Crustaceans, fish and shellfish are capable of accumulating elevated levels of domoic acid in their viscera and muscle tissue. Domoic acid was discovered in California in 1991. Shortly after, in 1993, CDPH initiated its marine biotoxin monitoring program and now, through a network of volunteers, routinely collects phytoplankton and bivalve shellfish samples from a number of sampling sites along the coast year-round. As elevated levels of domoic acid are identified in bivalve shellfish in a particular area, additional species (anchovies, sardines, crabs, lobster, etc.) are sampled and analyzed for domoic acid content. CDPH coordinates with CDFW to collect pre-season Dungeness crab samples each fall, collecting from representative locations along the coastline. This pre-season monitoring ensures that Dungeness crab do not contain elevated levels of domoic acid when the fishery opens.

In 2015/2016, there was an unprecedented bloom of *Pseudo-nitzschia* along the west coast that impacted California fisheries from Santa Barbara to the Oregon Border. CDPH found elevated levels of domoic acid in Dungeness and rock crab along a large portion of the California coastline. When CDPH finds that crab contain a level of domoic acid in the viscera that exceeds the federal action level, a health advisory is issued to notify the public of the risk of consumption. The 2015/16 season was also unique in that it was the first year that CDPH isolated domoic acid from the meat of both Dungeness and rock crab. Continued harvest of crab with elevated levels of domoic acid from an area under advisory and offering those crab for sale puts the fisherman and subsequent distributors and retailers in violation of the law.

During the 2015/2016 event, the Office of Environmental Health Hazard Assessment, in consultation with CDPH, determined that the fishery should be closed for both

recreational and commercial fishing in order to avoid potentially serious human health impacts. A recommendation to close the fishery was initiated by California state health agencies when Dungeness crab viscera or meat exceeded the action level.

FDA Action Levels

The US Food and Drug Administration (FDA) has established action levels for domoic acid in Dungeness crab at 20 ppm in the meat and 30 ppm in the viscera. These federal action levels are set forth in the FDA's Fish and Fishery Products Hazards Control Guide and are utilized in determining if a fishery product is adulterated. Under state and federal law, the manufacturing, selling, delivering, holding, or offering for sale of an adulterated food is a crime.

FDA levels for domoic acid were developed following a 1987 poisoning incident in Prince Edward Island, Canada. Following the consumption of locally harvested mussels, about 145 people were affected, 19 people hospitalized and three died. Individuals began experiencing symptoms in time periods ranging from 15 minutes to 38 hours, and symptoms ranged from mild, such as diarrhea, abdominal cramps, nausea and vomiting, to severe, including seizures, coma, and death. Irreversible memory loss also occurred in some people. Leftover food was available from 10 people to estimate the amount of domoic acid that led to adverse effects. Based on the evaluation, the smallest dose that made any of the 10 individuals ill was determined to be 60 milligrams (mg) of domoic acid. FDA divided this number by an uncertainty factor of 10 (giving a tolerable intake of 6 mg) and an estimated meal size of 250 grams (0.250 kg) to develop an action level of 20 ppm (mg/kg) for seafood.

Uncertainty factors account for deficiencies in the data such as small sample size, individual variability, lack of knowledge about effects on the fetus or multiple exposures, and for cases where a level causing an effect is used. In this case, illness occurred at the 60 mg dose. Subsequently, FDA determined an action level for viscera based on an estimate of the yield of viscera and body meat from one crab (150 g and 300 g, respectively). Accounting for the estimated potential contribution of domoic acid from the crab meat (1 mg), that left an allowable contribution of 5 mg from crab viscera toward the total tolerable intake. FDA divided this number by an estimated viscera meal size of 150 g to derive an action level of 30 ppm for viscera.

Under the provisions of 21 CFR Part 123, processors handling fishery products must conduct a hazard analysis and determine the hazards that are reasonably likely to occur for those products. For Dungeness crab, we know that domoic acid is a hazard that is likely to occur in the future. Processors handling fishery products with identified hazards likely to occur, must do so under a Hazard Analysis Critical Control Point Plan (HACCP Plan) that spells out what methods they are going to utilize to control the hazard and ensure that the necessary actions in the processing of those products occurs to eliminate the hazard.

Potential option for continued harvesting during an event

The agencies have reviewed the 2015/16 event and evaluated options for handling future events. While we believe that an event of this magnitude is unlikely to occur very often, we need to be prepared to respond when it occurs. The HACCP Plan/evisceration option discussed below could allow some level of continued fishing operations during domoic acid events, while ensuring the safety of the food supply and the integrity of the industry.

Under certain conditions, there may be an option to not close the fishery but to continue some limited fishing operations under an advisory when only the viscera is above the action level. However, this option is contingent, in part, on the ability of the industry to put the necessary control measures in place to ensure that the adulterated component of the crab (i.e., viscera) does not enter commerce.

Under certain circumstances, when an advisory is in place for Dungeness crab because the domoic acid level in the viscera exceeds the action level, CDPH registered processors could either eviscerate the Dungeness crab to remove the contaminated portion of the crab or part the crab out to remove the meat from the crab. The advisory could be put in place when the health agencies have assurance that the domoic acid levels in the crab meat taken from the fishery remain below 20 ppm. When meat levels are above that level there would be no salvageable portion of the crab that could be marketed. Operating under these types of protocols would require a documentation system that records the locations of catch and quantities of crabs landed by each fisherman and the maintenance of a paper trail of documentation through the processing of the crabs so that CDPH could audit the documentation and verify that whole crab caught in any areas under an advisory were not being diverted into the marketplace.

When an advisory is in place, the sale of live crab or whole crab caught in an advisory area would constitute the sale of adulterated products and be a violation of federal and state law, even if the area under an advisory was open to fishing. The responsibility to remove contaminated viscera from the crab cannot be passed down to the retailer or consumer.

We plan to participate in the upcoming Dungeness Crab Task Force Executive Committee conference call on August 26, 2016 to discuss this option and hear additional feedback and ideas from the Dungeness crab industry.