FDA Declines to Establish a Performance Standard for Vibrio in Raw Oysters

Stephanie Otts and Victoria Taravella

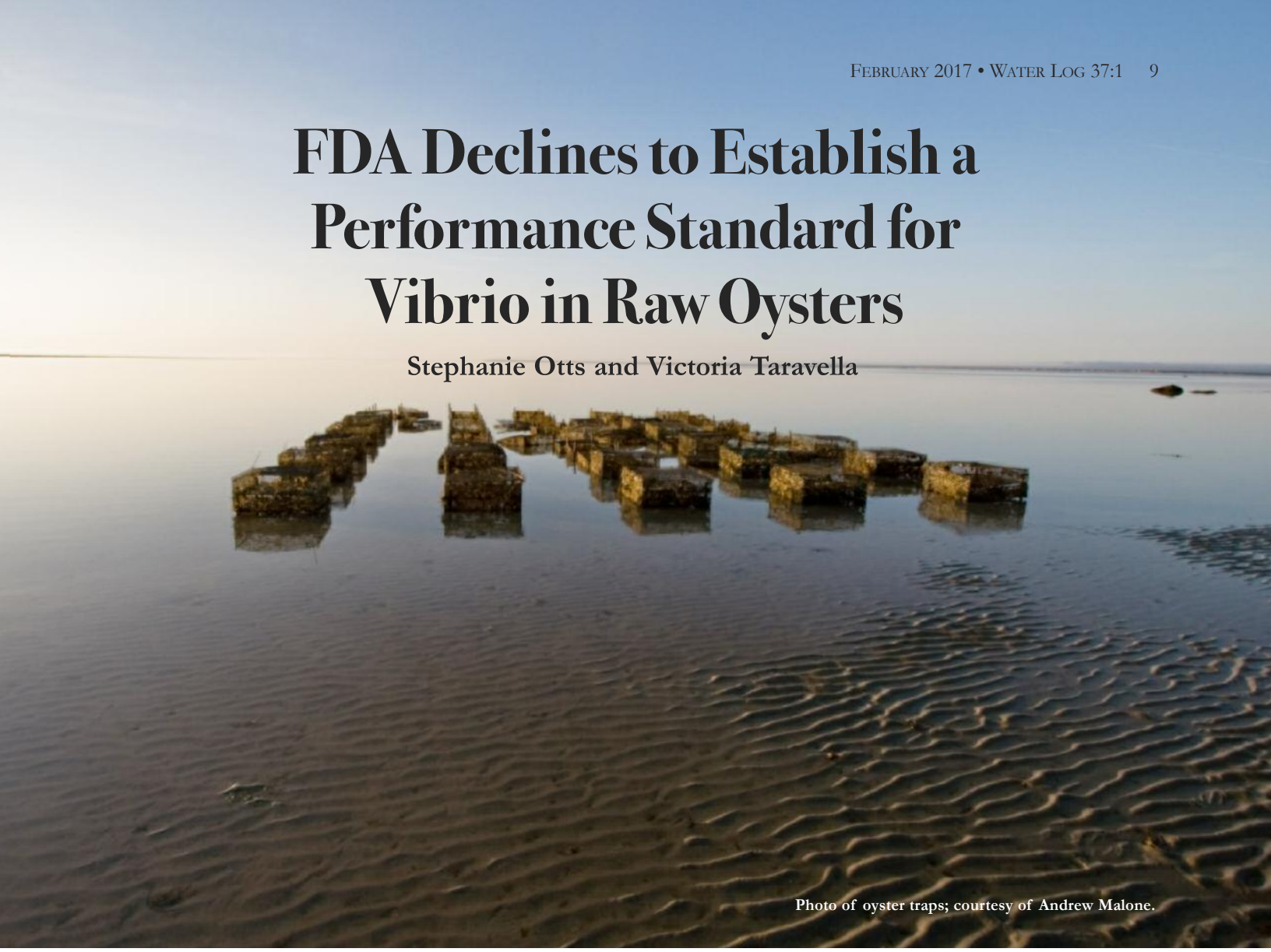

Photo of oyster traps; courtesy of Andrew Malone.

On November 30, 2016, the U.S. Food and Drug Administration (FDA) denied the petition of the Center for Science in the Public Interest (CSPI) to regulate V. vulnificus in shellfish. V. vulnificus, more commonly referred to as vibrio, is a naturally occurring bacteria in the marine environment that can cause infections through contact or ingestion. The bacteria blooms when water temperatures are warm for extended periods of time, such as during the summer months in the Gulf of Mexico. This bacterium can present a health risk throughout the year to individuals who consume raw oysters. In its petition, the CSPI requested the FDA take regulatory action to establish a performance standard of "non-detectable" in molluscan shellfish intended for raw consumption. The CSPI claims the enforcement of a performance standard would dramatically reduce the amount of deaths due to consumption of raw oysters containing V. vulnificus.

V. vulnificus can be found along all three coasts of the continental United States. The warm waters of the Gulf of Mexico promote the growth of the bacteria, especially during the summer months of May through September. A healthy person who comes into contact with vibrio may suffer symptoms similar to food poisoning that will usually pass in a few days' time. Individuals whose immune systems are compromised due to health conditions, such as diabetes or cancer, can experience severe and life-threatening infections. According to the Centers for Disease Control and Prevention, vibrio infections cause an estimated 80,000 illnesses and 100 deaths in the United States every year.[1]

The FDA works in partnership with the Interstate Shellfish Sanitation Conference (ISSC), a national organization of state shellfish regulatory officials, to provide guidance on standards and procedures for managing the safety of shellfish. The FDA and ISSC have

taken a number of non-regulatory steps to reduce the vibrio infection risks associated with the consumption of raw oysters. The ISSC members states, for example, are required to develop and implement vibrio management and control plans. States focus primarily on educating immunocompromised individuals regarding risks and enforcing strict post-harvest time-to-temperature controls. The FDA claims these efforts have resulted in a 30% reduction in illness reported nationwide and a 40% reduction in deaths in 2013 and 2014.[2]

Illness and deaths from the consumption of raw oysters, however, still unfortunately occur every year. The CSPI argued these state-led efforts are not enough to address the public health threat. The CSPI asserted in its petition that the control of vibrio should be a federal responsibility and wants the FDA to take regulatory action to eliminate the bacteria from oysters. The CSPI's petition called on the agency to establish a performance standard of non-detectable levels of V. vulnificus in molluscan shellfish intended for raw or processed raw consumption pursuant to § 104(b) of the Food Safety Modernization Act (FSMA). Section 104(b) authorizes the FDA to issue contaminant-specific guidance documents "when appropriate to reduce the risk of serious illness or death to humans."[3]

The CSPI asserted in its petition that the control of vibrio should be a federal responsibility and wants the FDA to take regulatory action to eliminate the bacteria from oysters.

On November 20, 2016, the FDA denied the CSPI's petition determining that a performance standard of non-detecable was not warranted at this time. The FDA acknowledged that they had the authority to issue contaminant-specific guidelines in certain circumstances but noted that nothing in the text of § 104(b) actually requires the agency to do so. In its denial letter, the FDA asserted that the significant reductions in oyster-related vibrio illnesses achieved in recent years was the result of increased industry compliance with state vibrio control

Photo of oysters; courtesy of Paul Asman and Jill Lenoble.

plan requirements. The FDA concluded that the most appropriate course of action at this time, given the agency's limited resources and competing priorities, was to continue to work cooperatively with the ISSC, states, and industry to implement risk reduction measures.

Despite the best efforts of the states and the oyster industry, some risk will always remain for consumers of raw shellfish. Vibrio is a naturally occurring bacteria that can never be entirely eliminated from the environment. Proper harvesting, handling, and processing techniques can reduce the levels of bacteria in raw oysters, but there is no legal standard. Individuals with compromised immune systems or other risk factors for vibrio infections should use caution when heading to a raw bar.

Stephanie Otts is Director of the Mississippi-Alabama Sea Grant Legal Program.
Victoria Taravella is a second-year law student at the University of Mississippi School of Law.

Endnotes

1. Vibrio species causing vibriosis, Centers for Disease Control and Prevention (last visited 2/16/17).
2. Letter from Nega Beru, Director, Office of Food Safety, Food and Drug Administration, to Michael Jacobson, Executive Director, Cetner for Science in the Public Interest, at 6 (Nov. 20, 2016).
3. 21 U.S.C. § 2201(b).