



State of Washington
DEPARTMENT OF FISH AND WILDLIFE

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Dockets Management Staff
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-0810 for “Equivalence Determination Regarding the European Union Food Safety Control System for Raw Bivalve Molluscan Shellfish.”

To Whom It May Concern:

The Washington Department of Fish and Wildlife (WDFW) appreciates the opportunity to comment on the proposal entitled *Equivalence Determination Regarding the European Union Food Safety Control System for Raw Bivalve Molluscan Shellfish* (hereafter: “proposal”). Our agency is charged with the preservation, protection, and perpetuation of the state’s fish, wildlife, and ecosystem resources. Among those resources are commercial shellfisheries that generate \$300 million in annual revenue, a shellfish aquaculture industry worth \$200 million in annual revenue, and recreational shellfisheries that attract over 200,000 in annual license sales. The shellfish economy in Washington is an important provider of jobs and commerce, particularly in rural and tribal communities, and shellfishing is a significant part of the identity of Washingtonians and Treaty tribes. The Food and Drug Administration (FDA) proposal will likely represent economic opportunity for some of our shellfish-dependent constituents, and we applaud the efforts at protecting human health that have contributed to this proposal. However, it also represents a risk to Washington shellfish interests and is a concern for one of our agency’s specific responsibilities: the management of shellfish disease risk to the state of Washington’s valuable shellfish resources.

The WDFW is working to prevent the introduction and spread of harmful disease-causing shellfish pathogens to Washington waters, which could permanently damage the state’s shellfish resources. While deemed safe from a human health standpoint, the importation of live molluscan shellfish represents risk for the introduction of harmful shellfish pathogens to receiving states. Of the seven mollusc diseases prioritized as *Reportable* by the World Organization for Animal Health (OIE), four have been documented and associated with substantial impacts in the European Union (EU). *Bonamia ostreae*, *Perkinus olseni*, and *Marteilia refringens* have all been confirmed in either or both Spain and the Netherlands, among other EU states; *Bonamia exitiosa* has been confirmed elsewhere in the EU. Two mollusc pathogens not yet listed by the OIE, *Vibrio tapetis* (causative agent of Brown ring disease of clams) and Ostreid herpesvirus microvariant (OSHV-1 μ var) are of critical concern to the state of Washington and have been documented in both Spain and the Netherlands. Both have been implicated in significant

damage to clam and oyster industries in a growing list of water bodies and their introduction to Washington would be potentially disastrous. This is not an exhaustive inventory, but a few examples of pathogens that may be unintentionally transferred to receiving states with live shellfish imports without proper precautionary measures.

It is unclear how the current proposal was developed under consultation with USDA-APHIS and does not appear to reflect any shellfish disease risk considerations (other than those relevant to human health) that may accompany the resulting commerce. Further, WDFW was not consulted on this proposal. Yet this proposal may represent serious risk of harm to the shellfish industries of receiving states, including Washington, and a comprehensive consideration of shellfish disease risk management should be part of any proposal to import live molluscan shellfish from the EU to the state of Washington.

WDFW seeks consultation with officials involved in considering this proposal to ascertain how the proposal addresses the risk of the transfer of shellfish pathogens with the shipment of live molluscan shellfish to Washington State and to request that the risk of transfer of shellfish disease be properly assessed, weighted, and mitigated in this proposal. We also seek improved communication to assure that WDFW is involved with future FDA processes associated with expansion of live shellfish imports, or development of similar import programs involving the state of Washington.

Sincerely,



Joe Stohr
Director

cc: Mr. Charlton Bonham, California Department of Fish and Wildlife
Mr. Scott Enright, Chair, Hawaii Department of Agriculture
Mr. David Fyfe, Northwest Indian Fisheries Commission
Mr. Glenn Haight, Executive Director, Alaska Department of Fish and Game
Mr. Curt Melcher, Director, Oregon Department of Fish and Wildlife
Mr. Ken Moore, Chair, Interstate Shellfish Sanitation Conference
Mr. Derek Sandison, Washington Department of Agriculture
Ms. Kim Stryker, Chair, Pacific Rim Shellfish Sanitation Association
Dr. Leah Tingley, U.S. Department of Agriculture-Animal and Plant Health Inspection
Service