Congress of the United States

Washington, DC 20510

April 18, 2016

The Honorable Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We understand the Food and Drug Administration (FDA) is undertaking efforts to end a seven-year impasse that has restricted trade of shellfish between the U.S. and the European Union (EU). The opportunity to reinstate this trade through an equivalency determination is significant and welcomed, but at the same time, we are concerned that the EU intends to limit the opportunities for trade to only two states at the outset, which will put Maine shellfish dealers at a disadvantage as the shellfish trade between the U.S. and the EU resumes. Therefore, we urge you to ensure that a clear path for the inclusion of all U.S. states compliant with the National Shellfish Sanitation Program be defined, so that all U.S. states wishing to explore this export opportunity are able to do so.

The equivalency determination currently being developed by the FDA should have included all states that meet the additional requirements for export to the EU, including Maine. In 2014, Maine became the first – and only – state to adopt the high pressure liquid chromatography (HPLC) biotoxin monitoring method, which can quantify levels of Paralytic Shellfish Poisoning (PSP) with a high level of accuracy. Moreover, it is the methodology used exclusively by many shellfish producing countries in the EU, such as Portugal, Ireland, Norway, France, and the United Kingdom. By transitioning to HPLC, Maine also has the unique ability to measure for other marine biotoxins of concern. Because Maine is the only state to use this advanced biotoxins monitoring program, it is well-positioned to meet the EU requirements. We are troubled that Maine has been left out of the equivalency determination process given its strong record on ensuring shellfish safety.

Limiting the equivalency determination process to only two states would disadvantage shellfish dealers in other states wishing to explore export opportunities. It is critical to Maine shell-fishermen that the FDA provides a detailed plan outlining a clear path for adding more states to this program. We also ask that the agency consult with its counterparts in the EU regarding this plan and reply to us in detail with what steps the EU has agreed to take.

We appreciate your consideration of our request. If you have any questions, please contact us or have your staff contact Patricia Aho of Senator Collins' office at (207) 622-8414, Kimber Colton of Representative Pingree's office at (202) 225-6116, Peter Benoit of Senator

King's office at (202) 224-3874, or Michael Sinacore of Representative Poliquin's office at (202) 226-1119. We look forward to hearing from you.

Sincerely,

Susan M. Collins
United States Senator

Angus S. King, Jr.
United States Senator

Chellie Pingree
Member of Congress

Bruce Poliquin
Member of Congress