



December 8, 2016

Johnathan Gerhardt
Interstate Shellfish Sanitation Conference
209-2 Dawson Rd
Columbia, SC 29223

Dear Mr. Gerhardt:

At the 2015 Interstate Shellfish Sanitation Conference (ISSC) in Salt Lake City, Utah the US Food and Drug Administration (FDA) submitted Proposal 15-208 to address the potential risk of *Clostridium botulinum* in Reduced Oxygen Packaging (ROP) containing shucked molluscan shellfish. The state voting delegates voted to refer Proposal 15-208 to an appropriate ISSC Committee for further discussion. In November, 2016 the ISSC held a ROP workshop to begin discussion of the Proposal. The workshop included members of the ISSC ROP Committee and a panel of subject matter experts with expertise and knowledge of the science and issues associated with *C. botulinum* and Reduced Oxygen Packaging.

The FDA appreciates the efforts of the ISSC in planning the ROP workshop held in Atlanta, Georgia on November 1-2, 2016. The workshop provided the participants with helpful insight from microbiologists, wholesalers, retailers, shellfish processors, the packaging industry, and state food safety inspection agencies. After careful consideration, the FDA would like to request that the ISSC take No Action on the proposed changes to the National Shellfish Sanitation Program (NSSP) Model Ordinance as recommended in Proposal 15-208. While the science is clear regarding ROP foods and the potential for *C. botulinum* toxin production, it is the view of the FDA that additional studies and discussion specific to molluscan shellfish are needed prior to adoption of ROP control strategies into the NSSP Model Ordinance. The ISSC ROP Committee recommended, with ISSC Executive Board concurrence, that additional information be gathered and that studies to be considered to assess the potential risk of *C. botulinum* in shucked molluscan shellfish packaged in ROP containers. FDA concurs with those recommendations and will provide assistance as appropriate.

As always, FDA appreciates the support of the ISSC as we work cooperatively to further examine ROP and molluscan shellfish. Should you have any additional questions, please contact Melissa Abbott, FDA's ISSC liaison and Executive Board representative, at melissa.abbott@fda.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul DiStefano". The signature is fluid and cursive, with a large, stylized "P" and "D".

Paul DiStefano
FDA Division of Seafood Safety
Center for Food Safety
and Applied Nutrition

cc:

HFS-300: N. Beru, W. Jones

HFS-325: P. Koufopoulos, J. Forrest, M. Abbott, F. Burditt, M. Losikoff

HFR-PA3560: K. Phelps

HRS-450: G. Skinner, Y. Song

FDA National Shellfish Team

Ken Moore, ISSC Executive Director