

Proposal Subject: ISSC Constitutional Cost-Benefit Requirement for New Proposals that have a Significant Financial Impact on the States and Shellfish Industry

Specific NSSP Guide Reference:

Text of Proposal/ Requested Action: Article XIII. Procedure for the Submission of Proposals

Section 1. The Executive Director shall provide each registrant of the preceding Conference meeting at least one hundred sixty-five (165) days prior to the next Conference meeting with forms on which proposal for problems are to be submitted to the Executive Director for assignment to the appropriate Task Force.

Section 2. All proposals must be submitted to the Executive Office no later than one hundred twenty (120) days prior to the Conference meeting.

Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force.

Section 4. Proposals submitted by any Conference participant that may have a significant cost to implement by either the SSCA or the shellfish industry must include an independent cost benefit analysis and an economic impact study.

Section ~~5~~⁴. The Executive Director shall review and assign all problems or proposals received for Task Force and Conference deliberation. Problem or proposal assignment shall be made according to subject matter and in accordance with Article XIII. Section 4., Section 5., Section 6., and Section 7. of the Constitution of the Conference.

Section ~~6~~⁵. Task Force I - Growing Areas: all proposals submitted to the Conference dealing with the classification or patrol of shellfish growing waters, relaying, training and research, or similar items concerning growing areas shall be assigned to Task Force I by the Executive Director.

Section ~~7~~⁶. Task Force II – Harvesting, Handling, and Distribution: all proposals submitted to the Conference dealing with the sanitation of harvesting, depuration, processing, labeling, transporting, storage, fill or content, training and research, or similar items concerning processing and distribution shall be assigned to Task Force II by the Executive Director.

Section ~~8~~⁷. Task Force III - Administration: all proposals submitted to the Conference dealing with Conference agreements, memorandums of understanding, complaints and challenges of reciprocity and program evaluations, or similar items, or items not specifically relating to Task Force I or II shall be assigned to Task Force III by the Executive Director.

Section ~~9~~⁸. The Executive Director shall provide the appropriate shellfish control authorities in each state and all members, at least ninety (90) days prior to each Conference meeting, with the proposals to be discussed under the heading of Unfinished Business.

Section ~~10~~⁹. Proposals submitted after the deadline, established in Article XIII Section 2 of the Constitution, will be reviewed and may be accepted by the Executive

Board for Task Force Consideration. The Executive Board will use the following criteria in accepting late proposals.

- Subdivision a. Why is the proposal being submitted after the deadline?
- Subdivision b. Was the information available prior to the deadline?
- Subdivision c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC?
- Subdivision d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change?

Section ~~11~~¹⁰. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.

Section ~~12~~¹¹. The Proposal Review Committee will review and prioritize proposals for Task Force consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.

Public Health Significance:

Cost-Benefit Analyses and Economic Impact Studies are required by Federal and State Agencies prior to imposing new regulations. For too many years the ISSC through amendments made to the NSSP without any regards to the costs imposed on the SSCA and Shellfish Industry to implement the new guidelines.

Cost Information (if available):

The cost to conduct cost-benefit analyses and economic impact studies will be much less on the SSCA'S and Shellfish Industry than the cost to implement by the SSCA's or by the shellfish industry.

Action by 2011 Task Force III

Recommended referral of Proposal 11-305 to the appropriate committee as determined by the Conference Chairman. The committee is instructed to identify ways to better utilize the cost information portion of the proposal submission form.

Action by 2011 General Assembly

Adopted the recommendation of Task Force III on Proposal 11-305.

Action by FDA February 26, 2012

Concurred with Conference action on Proposal 11-305.

Action by 2013 Proposal Review Committee

Recommended no action on the proposed change to the procedures for submission of Proposals. The committee further recommended that an appropriate committee, as determined by the Conference Chair, work with the Executive Office to develop Proposal Submission Instructions. In addition to technical instructions about how to use the form, the instructions should address each field of the submission form and shall be completed prior to the next call for proposals. The instructions for the "cost" field should provide further guidance, including examples, of the type of cost information that may be useful to those reviewing the proposal.

Action by 2013 Task Force III

Recommended adoption of the Proposal Review Committee recommendations.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force III on Proposal 11-305.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 11-305.

H.R.2751
FDA Food Safety Modernization Act
SEC. 114. REQUIREMENT FOR GUIDANCE RELATING TO
POST HARVEST PROCESSING OF RAW OYSTERS.

- (a) In General- Not later than 90 days prior to the issuance of any guidance, regulation, or suggested amendment by the Food and Drug Administration to the National Shellfish Sanitation Program's Model Ordinance, or the issuance of any guidance or regulation by the Food and Drug Administration relating to the Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration (parts 123 and 1240 of title 21, Code of Federal Regulations (or any successor regulations), where such guidance, regulation or suggested amendment relates to post harvest processing for raw oysters, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report which shall include--
- (1) an assessment of how post-harvest processing or other equivalent controls feasibly may be implemented in the fastest, safest, and most economical manner;
 - (2) the projected public health benefits of any proposed post-harvest processing;
 - (3) the projected costs of compliance with such post-harvest processing measures;
 - (4) the impact post-harvest processing is expected to have on the sales, cost, and availability of raw oysters;
 - (5) criteria for ensuring post-harvest processing standards will be applied equally to shellfish imported from all nations of origin;
 - (6) an evaluation of alternative measures to prevent, eliminate, or reduce to an acceptable level the occurrence of foodborne illness; and
 - (7) the extent to which the Food and Drug Administration has consulted with the States and other regulatory agencies, as appropriate, with regard to post harvest processing measures.
- (b) Limitation- Subsection (a) shall not apply to the guidance described in section 103(h).
- (c) Review and Evaluation- Not later than 30 days after the Secretary issues a proposed regulation or guidance described in subsection (a), the Comptroller General of the United States shall--
- (1) review and evaluate the report described in (a) and report to Congress on the findings of the estimates and analysis in the report;
 - (2) compare such proposed regulation or guidance to similar regulations or guidance with respect to other regulated foods, including a comparison of risks the Secretary may find associated with seafood and the instances of those risks in such other regulated foods; and
 - (3) evaluate the impact of post-harvest processing on the competitiveness of the domestic oyster industry in the United States and in international markets.
- (d) Waiver- The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.
- (e) Public Access- Any report prepared under this section shall be made available to the public.

United States Senate
WASHINGTON, DC 20510

January 25, 2011

Mr. Ken Moore
Executive Director
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223

Dear Mr. Moore:

As you know, Congress recently passed P.L. 111-353 the "FDA Food Safety Modernization Act." We were proud to author section 114 of the law pertaining to the regulation of raw oysters. We wrote this language to provide the Secretary a waiver only if state regulators, the oyster industry, and Interstate Shellfish Sanitation Conference's, (ISSC), voting delegates approved the regulation or guideline proposed by the Food and Drug Administration or ISSC. As the ISSC moves forward, we wanted to clarify the intent of section 114(d) which states:

Waiver- The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.

This clearly states that the oyster industry through ISSC should be an intricate part of the process. Specifically, the language is intended to ensure that new guidelines or regulations cannot move forward without the consensus from the oyster industry.

Thank you for the opportunity to clarify the intent of Congress in these matters. We look forward to working with you and the Interstate Shellfish Sanitation Conference on the implementation of the FDA Food Safety Modernization Act.

Sincerely,



David Vitter
United States Senator



Mary Landrieu
United States Senator