February 7, 2018

Mr. Johnathan Gerhardt, Chair
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, South Carolina 29223

Dear Mr. Gerhardt:

The FDA is submitting this letter in response to the Summary of Actions from the 2017 biennial meeting of the Interstate Shellfish Sanitation Conference (ISSC) held October 14 - 19, 2017 in Myrtle Beach, South Carolina. The FDA concurs with action taken by the ISSC on all proposals deliberated with the exception of Proposal 11-103. Additionally, the Agency has provided comments and recommendations for ISSC consideration on Proposals 17-100, 17-217 and 17-305.

Proposal 11-103:

The FDA does not concur with Conference action to adopt proposal 11-103 as written. The final language adopted by the Conference includes language that is written in the form of guidance (as highlighted below) but is included in the MO under Chapter XV that are requirements for Depuration. The current adopted language reads:

K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD).

If the conditionally restricted growing area from which the shellstock is being depurated is impacted by wastewater treatment system discharge (generally that section of the conditionally restriced growing area located within the 300:1 to 1000:1 dilution lines), then supplemental requirements for depuration using MSC viral controls may be required. Depuration using MSC viral controls may be seasonally limited and may be species and depuration facility specific. Contaminant reduction studies as described in (1) below are recommended unless the SSCA and the Depuration Facility Operator have significant experience with the depuration process using MSC viral controls.

It is the FDA's position that shellfish harvested from growing areas located within the 300:1 to 1000:1 dilution lines need to be held and processed under prescriptive controls to prevent shellfish borne illnesses. As written, these necessary controls are optional and implemented at the discretion of the depuration processor. The FDA does not concur with setting a precedent for harvesting product adjacent to a wastewater treatment plant discharge within the conference recognized 1000:1 dilution zone with optional controls to address a legitimate viral concern. The FDA believes that such a precedent could place the public at risk from potentially unsafe product that could enter the market if these "recommended" controls are ignored.

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For over a decade, the FDA has conducted many collaborative studies with state shellfish control authorities and some industry members, which has provided the conference with the science to support various proposed uses of MSC. The studies show that when necessary controls are in place and adhered to, harvesting within a 1000:1 dilution zone can be supported. Thus, except for the language written in the form of guidance, the FDA generally agrees with the modified language including striking the requirement that would delete water quality monitoring if the end point meat standard is implemented.

The FDA attempted to address the conflicting language highlighted above during the conference with alternative language as follows:

K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD).

Shellfish intended for depuration from waters impacted by wastewater treatment discharge at dilution levels within 1000:1 but no less than 300:1 or the EPA Regulated Mixing Zone (whichever is greater) shall meet supplemental requirements for using MSC viral controls.

The FDA's proposed changes not only address the concerns of placing guidance language within a requirements section but also addresses harvesting closer to the wastewater treatment plant outfall within the 1000:1 dilution zone. The FDA explained the Environmental Protection Agency (EPA) requirements for regulated mixing zones (RMZs) do not include any specific minimum dilution requirements adjacent to a wastewater discharge. Rather, RMZs are determined on a case-by-case basis for each regulated discharge and are based upon meeting priority pollutant criteria at the boundary of the RMZ. Thus, it is conceivable that the size of some RMZs could be within 300:1 but in some circumstances, may be greater than 300:1. The FDA's proposed language would prevent the harvest of product from within an RMZ in which toxic pollutants do not meet established EPA criteria.

It is therefore the FDA's recommendation for the ISSC to reconsider the FDA's proposed language presented at the conference. If a compromise agreeable by ISSC to address FDA's concerns cannot be reached, then the Agency would not concur with conference recommendation on proposal 11-103 and would recommend that proposal 11-103 be sent back to the appropriate committee as determined by the conference chairman to address the FDA's concerns.

Proposal 17-100:

While the FDA concurs with the referral of Proposal 17-100 to the appropriate committee, the FDA would like to reiterate the current definition of a marina in the Model Ordinance, which reads as follows:
"**Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is:
(a) Used for docking or otherwise mooring vessels; and
(b) Constructed to provide temporary or permanent docking space for more than ten boats."

In the FDA1989 Guidance, "Evaluation of Marinas by State Shellfish Sanitation Control Officials," the Agency provided guidance for the uniform application of the NSSP criteria for the

evaluation and classification of shellfish growing waters in and around docks, marinas, or other boat mooring areas and has taught that application in the Sanitary Surveys of Growing Areas course. The FDA considers mooring areas to be included in the definition of "marina" and believes that the mooring area proper should be classified as conditionally approved, conditionally restricted, restricted, or prohibited when more than ten (10) boats are present; depending on the analysis conducted combined with the water quality in the area. The FDA understands that this issue will be discussed further by the committee, but will continue to cite deficiencies related to mooring areas in Program Element Evaluation Reports where appropriate and based on the current definition and policy until this matter is further resolved. The FDA encourages prompt action by the committee with interim Executive Board action to address this concern.

Proposal 17-217:

While FDA agrees with the intent of Proposal 17-217, FDA disagrees with the content of the language that was agreed upon by the ISSC. FDA believes that the language as adopted would cause changes in the program that aren't necessary to accomplish the intent of the proposal and believes that the intent can be accomplished in a more effective manner. The public health significance and concern expressed in Proposal 17-217 was, "there should not be any harvester tags at restaurants because only harvesters who are also certified dealers can sell directly to retail or ship interstate, making harvesters an unapproved source. When both tags are affixed to the container, there will also be a blank dealer's tag that may potentially be used by an unauthorized person." The language adopted by the ISSC requires removal of the harvester tag and replacement with a dealer's tag containing the information in Chapter X. .05 B. FDA believes that a more appropriate way to handle this is to delete the language in Chapter X. .05 B. (3), so that all information must be included on the dealer's tag, regardless of whether a harvester tag appears on the container. The language approved by the ISSC would eliminate the possibility of blank dealer tags being used by unauthorized persons. However, it is FDA's understanding that some states have requirements to include harvester tags on containers and approving alternate language would not affect current practices in those statesand would also address the concern expressed in the proposal that the dealer's tag should include all the required information. There has also been concern expressed to FDA that the combination dealer/harvester tags, dealer tag on one side and harvester tag on the other, would no longer meet the requirements of Chapter X. .05 B. FDA requests that the Executive Board consider this alternate action and agree to delete the language in Chapter X. .05 B. (3) as an interim measure for ISSC concurrence at the 2019 Biennial Meeting.

Proposal 17-305:

While the FDA concurs with referral of Proposal 17-305 to an appropriate committee and welcomes discussion of the points raised by the proposed language, the FDA would like to ask that the committee review and consider the language that currently exists in the FDA's Molluscan Shellfish Compliance Program and the proper placement of any new language that is proposed. If requirements are to be placed on the FDA evaluations, such language does not belong in the Model Ordinance, but rather in the Compliance Program or the ISSC By-Laws and Procedures, under Procedure IX "Procedures for Handling Complaints and Challenges

Regarding the Adequacy of Certification Controls" in Section 2, which discusses "When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance." The FDA is open to discussing ways to recognize immediate (within 30 days) correction of deficiencies, but also realizes there are scenarios that would limit FDA's ability to verify corrections within a prescribed timeframe. The proposal requests that the FDA Shellfish Specialists provide the specific NSSP Model Ordinance reference for each deficiency cited during an evaluation. The FDA's current Molluscan Shellfish Compliance Program (CPGM 7318.004), includes language to address this request. It states: "When deficiencies are noted, the specific NSSP Model Ordinance reference for each deficiency should be included in the narrative." (CPGM 7318.004, imp. date 09/20/2017, Part III.2.A (pg. 15)). Additionally, Attachment A of the CPGM (Program Element Evaluation Report (PEER)) instructs Shellfish Specialists to "Provide a detailed description of deficiencies found during evaluation (deficiencies must be documented)." The FDA will ensure that shellfish specialists follow this guidance. Our goal is to be consistent and transparent in program evaluations and welcomes open discussion for improving communications with State Authorities regarding program evaluation.

As always, the FDA looks forward to its continued cooperative relationship with the ISSC as we work jointly to strengthen the shellfish safety provisions of the NSSP and protect public health.

Sincerely,

William R. Jones, PhD, Acting Director
Office of Food Safety
Center for Food Safety
and Applied Nutrition

cc:
Ken Moore, Executive Director
HFS-325, P. Koufopoulos, M. Abbott
FDA National Shellfish Team