FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

February 21, 2020

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 2019 biennial meeting of the Interstate Shellfish Sanitation Conference (ISSC) held October 5 – 10, 2019, in San Diego, California. The FDA concurs with action taken by the ISSC on all proposals with the exception of Proposal 17-100. Additionally, the FDA is providing comments and recommendations for the ISSC on Proposals 17-206 and 19-241.

Proposal 17-100:

The FDA concurs with the primary purpose of Proposal 17-100, which was to recognize potential pollution differences between marina and mooring areas. However, the FDA has identified several inconsistencies in the adopted language that must be addressed before FDA can provide concurrence.

FDA Concerns:

1. Mooring Area Definition and Chapter IV@.06A Language: The newly adopted definition for a mooring area in the Section I. Purpose & Definitions is not consistent with language included in Chapter IV@.06A and may cause confusion.

   The FDA suggests the term "Public entity," included in the new language included in Chapter IV @ .06 A, be deleted. The term, "Public entity" is limiting and not consistent with the adopted language for the definition of a mooring area. The inclusion of "Public entity" does not provide a full characterization of all mooring areas that should be considered in the classification of shellfish growing areas. The phrase "where there is anchoring of boats" is redundant and should be deleted. The classification requirements of a mooring area in Chapter IV@.06A should be consistent with the definition of a mooring area in Section I. Purpose & Definitions.

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Suggested Change to Newly Adopted Chapter IV@.06A:
Mooring Area Proper. The area within any ~~Public entity~~ designated mooring area~~, where there is anchoring of boats~~, which is in or adjacent to a shellstock growing area shall be classified as, conditionally approved, conditionally restricted, restricted or prohibited.

2. Pollution Assessment: The newly adopted language in Chapter IV@.06 requires a "pollution assessment" to be conducted prior to classifying any mooring area as Conditionally Approved, Conditionally Restricted, or Restricted. The FDA has concerns that the pollution assessment requirements are not specific enough and may cause confusion and inconsistencies during FDA evaluations. The FDA wants to ensure that the State Control Authority (Authority) is informed as to what will be expected by FDA in an acceptable pollution assessment for mooring areas. The FDA would like to clarify the following points to make sure that a complete pollution assessment is conducted.

   a) Pollution Assessment Guidance: The FDA has concerns that the "pollution assessment" language describing the new requirements in Chapter IV. @.06(1) is not specific enough given that the pollution assessment will be used to allow classifications other than prohibited. Our primary concern would be the use of Conditionally Approved in the open status. Chapter IV@,06A.(2), states that, *"(2) After assessment determines that the mooring area is not a pollution source and it is documented in the Conditional Area Management Plan, the area can be placed in the open status."* To address this, the FDA suggests providing guidance for conducting a mooring area pollution assessment through updating the 1989 FDA Guideline – Evaluation of Marinas by State Shellfish Sanitation Control Officials. This 1989 document is used as part of the FD242 Growing Area Course. This document is not presently included in the NSSP Guide. FDA would work with the Growing Area Classification Committee to update this document and submit it as a proposal for inclusion in the NSSP Guide as a guidance document.

   b) Pollution Assessment and Federal No Discharge Zone (NDZ): The NDZ is only one factor to consider in conducting a pollution assessment when classifying a growing area with a mooring area as Conditionally Approved in the open status. The FDA has concerns with the addition of Chapter IV@.06A(g), *"(g) Documentation, verification and enforcement of federal No Discharge Zones, and locally well enforced no discharge and occupancy regulations or by-laws."* The FDA is concerned that documentation of the NDZ designation may be considered by the Authority to be all that is needed for a pollution assessment and pollution control for a mooring area to be classified as Conditionally Approved in the open status. The FDA does not consider the NDZ designation to be a sufficient standalone pollution assessment, control mechanism, or justification for classifying a mooring area as Conditionally Approved in the open status. As stated in the new language, documentation, verification and enforcement of NDZ and locally well enforced no discharge and occupancy regulations or by-laws will be necessary in the assessment and for review in FDA evaluations.

In addition, Section 312 of the Clean Water Act (CWA) contains the principal framework for domestically regulating sewage discharges from boats and is implemented jointly by the U.S. Environmental Protection Agency (EPA) and the U.S. Coast Guard (USCG). "Sewage" is defined under the CWA as "human body wastes and the waste from toilets and other receptacles intended to receive or retain body wastes" and is prohibited in a NDZ. Graywater is not defined as "sewage" and is not prohibited under the NDZ. Graywater may contain high levels of human bacteria and viruses and pose a significant human health risk when present and this too should be considered in the pollution assessment. The FDA suggests that the guidance document mentioned in a) above include guidance for assessing "No Discharge Zones."

3. Areas Where There are Twenty (20) or Less Boats Moored: The FDA interprets the newly adopted language in Chapter IV@.06 for mooring areas, defined as "*any water area that is used to provide temporary or permanent anchorage for more than twenty (20) boats,*" as a component of the overall sanitary survey requirements in Chapter IV@.01. The sanitary survey currently requires an evaluation of all actual and potential pollution sources that may impact a shellfish growing area. As a fundamental premise, FDA considers every boat (boat, houseboat, barge, etc.) within a growing area to have the potential to discharge human waste and transmit pathogens; therefore, areas where there are 20 or less boats moored, still need to be evaluated as a potential pollution source and documented in the sanitary survey.

   Any congregation of boats, including those below the number required for the mooring area definition, must be assessed. In addition, the pollution assessment of mooring areas must be conducted during time of use, e.g. weekends, holidays, and times of peak usage (summer). This guidance should also be included in the guidance document mentioned in a) above.

4. FDA has identified additional places in the NSSP MO that should be updated to include mooring areas.

- Section II Model Ordinance - Chapter I Shellfish Sanitation Program
  Shellfish Sanitation Program Requirements for the Authority
  @.03 Evaluation of Shellfish Sanitation Program Elements
  B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:
  2. Growing Areas
  Requirements for evaluation of the shellfish growing area program element shall include at a minimum:
  a. Records audit of sanitary survey;
  b. Bacteriological standards;
  c. Growing area classification;
  d. Marine Biotoxin control; and
  e. Marinas
  f. Mooring Areas.

- Section II Model Ordinance – Chapter IV@.03C(3)(b)(i)

  When the conditional management plan is based on the absence of pollution from marinas and/or mooring areas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.

- Section II Model Ordinance – Chapter IV@.03E(1)

  E. Prohibited Classification

  (1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas and/or mooring areas. The Authority, however, may use the prohibited classification for these waters.

Proposal 17-206:

FDA concurs with the Conference's action to refer Proposal 17-206 to committee. FDA suggests this committee be formed as soon as possible and that the Executive Board consider the committee's recommendations on appropriate changes to the June 22, 2018 Guidance which was provided to states. The critical issues that should be considered by the committee are counting of culture independent diagnostic testing (CIDT) positive cases and case attribution where multiple sources are identified. The committee would deliberate and decide on appropriate attribution. The attribution of illnesses is a great public health concern as it impacts closure and harvest controls; and thus, prevention of further illnesses. The FDA encourages the expeditious formation of the committee and looks forward to continued engagement in this process.

Proposal 19-241:

FDA concurs with the Conference's action to refer Proposal 19-241 to committee. FDA would like to encourage the Conference Chair to direct the *Vv* Illness Review (*Vv*IR) committee to begin discussions on proposal 19-241 as soon as possible. Identification of more appropriate metrics to assign *Vibrio vulnificus* (*Vv*) cases will greatly facilitate the *Vv*IR committee's standing charge. The ISSC with FDA concurrence has opted not to accept each *Vv* case that is reported but to critique the merits to determine if each case is indeed septicemia from a commercial oyster consumption illness. As the uses of *Vv* data have changed over the life of the committee, this metric has become less useful. If the committee is to continue to be useful in their role, each case must be deliberated in a standardized manner, not by examining for septicemia, but determining if each case meets a clinical definition.

FDA supports this CDC drafted proposal intended to eliminate the septicemia qualification from Procedure XVI when case counting for *Vv* illness review. The suggested new metric to be used would be severe illness in the form of bacteremia, not blood infection. The proposal language includes cooked oysters and eliminates the question of how well the oysters are cooked. Additionally, the language considers only clinical symptoms such as fever, shock, listed sequelae or death. This proposal includes a table of specimen sources likely to indicate invasive disease rather than discounting stool or wound specimens.

In conclusion, FDA was encouraged by the transparent discussions and positive engagements that occurred during the biennial meeting. As always, the FDA looks forward to its continued cooperative relationship with the ISSC and through the newly formed Regulatory Relationships Committee, as we work jointly to strengthen the shellfish safety provisions of the NSSP and protect public health.

Sincerely,

Mark A. Moorman -S

Digitally signed by Mark A. Moorman -S
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Mark Moorman, Ph.D.,
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