# 2020 ISSC Update
# Keith Skiles, Executive Director

# 2020-2021 Executive Board

| | |
|---|---|
| Kohl Kanwit | Chair (ME) |
| Robert Schuster | Vice Chair/ Region 2 Regulatory (NJ) |
| Eric Hickey | Region 1 Regulatory (MA) |
| Lori Howell | Region 1 Industry (ME) |
| Steve Fleetwood | Region 2 Industry (NJ) |
| Michael Bott | Region 3 Regulatory (DE) |
| Pete Jensen | Region 3 Industry (MD) |
| Shannon Jenkins | Region 4 Regulatory (NC) |
| Barry Hurt | Region 4 Industry (FL) |
| Erik Broussard | Region 5 Regulatory (MS) |
| John Tesvich | Region 5 Industry (LA) |
| Kim Stryker | Region 6 Regulatory (AK) / AFDO |
| Diani Eckerson | Region 6 Industry (WA) |

# 2020-2021 Executive Board
(continued)

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|---|---|
| Johnathan Gerhardt | Non-Producing State (NM)/Past Chair of Executive Board |
| Bruce Flippens | Non-Producing State (DC) |
| Jon Strauss | Non-Producing State (CO) |
| Melissa Abbott | FDA |
| Jon Bell | NMFS |
| Bill Kramer | EPA |
| Keith Skiles | ISSC Executive Director |
| David Fyfe | Northwest Indian Fisheries Commission |
| Keith Jackson | Retail Advisory Representative |
| Laurie Farmer | FDA ORA Advisor |
| Erin Stokes | CDC Liaison |

# COVID-19

The ISSC Executive Board adopted several strategies to help the states and FDA address workload concerns resulting from travel and field work limitations imposed as a result of COVID-19 concerns and response activities.

# 2019 ISSC Proposal Package

**28 Proposals Referred from Previous Conferences**

**103 New Proposals**

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|---|---|
| Task Force I<br>(Growing Area Classification) | 67 |
| Task Force II<br>(Harvesting/Processing/Distribution) | 48 |
| Task Force III<br>(Administrative) | 16 |

# 2019 ISSC Proposal Package

Conference Adopted 62 Proposals
51 Resulted in Program Changes

| | |
|---|---|
| Growing Area Classification | 27 |
| Harvesting/Handling/Distribution | 31 |
| Administrative | 4 |

# 2019 Summary of Actions Review Process

**Summary of Actions Submitted to FDA**
**November 7, 2019**

**FDA Review**

**FDA Response to ISSC**
**Summary of Actions**

**2019 Version of NSSP**
***Expected to be available on the FDA Website Soon***

**FDA Website Link**
**http://www.fda.gov**

**ISSC Website Link**
**www.issc.org**
**Click on "NSSP Guide"**

# FDA Response to 2019 Summary of Actions

FDA responded to the Summary of Actions on February 21, 2020. FDA did not concur with ISSC action on Proposal 17-100 with the following comments:

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

# FDA Response to 2019 Summary of Actions

## Proposal 17-100 (continued):

**Proposal 17-100**

**Mooring Area Definition and Chapter IV@06A Language**

The newly adopted definition for a mooring area in Section I. Purpose and Definitions is not consistent with language included in Chapter IV@.06A and may cause confusion. The FDA suggests that the term "Public Entity", included in the new language 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 ISSC Executive Board took interim action removing the term "Public Entity" as suggested.

# FDA Response to 2019 Summary of Actions

## Proposal 17-100 (continued):

**“Pollution Assessment”**

The newly adopted language in Chapter IV@06 requires a “pollution assessment” 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 create confusion and inconsistencies during FDA evaluations.

To address this situation, in FDA intends to work with the Growing Area Classification Committee to update the 1989 guidance for evaluation of marinas and submit it as a proposal for inclusion in the NSSP Guide.

# FDA Response to 2019 Summary of Actions

## Proposal 17-100 (continued):

**Federal No Discharge Zones**

FDA also expressed concern that based on the newly adopted language in 17-100, documentation of a NDZ designation may be all that a State Authority will feel is needed for a pollution assessment and pollution control for a mooring area to be classified as Conditionally Approved in the open status.

As stated in the new language, documentation, verification, and enforcement of a NDZ and locally well enforced NDZ and occupancy regulations or by-laws will be necessary in the assessment and for review in FDA evaluations.

# FDA Response to 2019 Summary of Actions

## Proposal 17-100 (continued):

**Graywater concerns**

FDA pointed out that Section 312 of the Clean Water Act does not include graywater in the definition of "sewage", and is not prohibited from discharge in a NDZ, and therefore should also be considered in the pollution assessment.

FDA suggested that the updated guidance document include guidance for NDZ assessment.

# FDA Response to 2019 Summary of Actions

## Proposal 17-100 (continued):

**Missing mooring area references**

FDA noted that the following sections of the Guide had references regarding marinas that needed to include mooring areas since they are now defined differently:

- Chapter I @03.B2
- Chapter IV @03.C(3)(b)(i)
- Chapter IV @03.E(1)

# FDA Response to 2019 Summary of Actions

## Proposal 17-206

**Culture Independent Diagnostic Testing (CIDT)**

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 CIDT positive cases and case attribution where multiple sources are identified.

# FDA Response to 2019 Summary of Actions

**Proposal 19-241** *Vibrio vulnificus* Control Plan

FDA concurs with the Conference's action to refer Proposal 19-241 to committee with the following comments:

- The Conference Chair be encouraged to direct the *Vv* Illness Review Committee (*Vv*IR)to begin discussions as soon as possible;
- Identification of more appropriate metrics to assign *Vv* cases will greatly facilitate the *Vv*IR committee's standing charge.
- As the uses of *Vv* data have changed over the life of the *Vv*IR Committee, case counting based on septicemia from commercial oyster consumption illness 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 Response to 2019 Summary of Actions

**Proposal 19-241** *Vibrio vulnificus* Control Plan (continued)

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.

# Committee Activities

- **Laboratory Committee**
  - Currently reviewing several methods for approvals
- **NSSP Evaluation Steering Committee**
  - Charged with establishing guiding principles to be used by the Plant Evaluation, Growing Area and Control of Harvest Evaluation Committees to promote uniformity among the program elements.
- **NSSP Plant Evaluation Criteria Committee**
  - Developed recommendations for revisions to the Plant In-Field Evaluation Criteria.

# Committee Activities

*(continued)*

- **Research Guidance Committee**
  - Identify research needs related to molluscan shellfish safety. Committee developed a research priority survey. The memberships of ISSC was surveyed. The survey information was used to establish ISSC research priorities for the 2020 ISSC RFP.

# Committee Activities

*(continued)*

- **Research Management Committee**
  - Reviewed final reports of prior grant awards.
    - Auburn University - Assessing Geographic Variation on Re-Submergence Time to Reduce the Vibrio Risk Associated with Routine Oyster Aquaculture Handling
    - University of New Hampshire - Oyster Culture and Harvest Practices to Reduce Pathogenic Vibrio parahaemolyticus Concentrations in the Northeast US
    - Virginia Institute of Marine Sciences - Influence of Plankton Community Composition and Abiotic Environmental Factors on the Dynamics of Total and Pathogenic Vibrio parahaemolyticus in Oysters, Water and Sediment
  - Final reports are posted on the ISSC website.

# Committee Activities

*(continued)*

- **Research Management Committee**
  - Reviewed proposals submitted based on the ISSC 2020 RFP.
  - Based on their review scoring, the following proposals were accepted:
    - Bigelow Laboratory for Ocean Science: Investigating the potential to reduce time and cost for analysis of PST in the Gulf of Maine through amendment of the PCOX-LC-FLD method
    - Virginia Department of Health: Biotoxin monitoring and management using flow-through real-time sampling and toxin tracking
    - Louisiana State University: Rapid cost-effective detection of vibrio in shellfish using loop-mediated isothermal amplification (LAMP): visual methods for field diagnosis of *Vibrio parahaemolyticus* and *Vibrio vulnificus*

# Other ISSC Activities

- ISSC/FDA Training
  - Joint Advisory Group Prioritization for Funding of Training
  - ISSC Training Committee
    - Illness Outbreaks – An overview and interpretation of the 2019 Proposals adopted amending Chapter II
    - 2017 NSSP Model Ordinance Chapter VI. Shellfish Aquaculture

# ISSC Committees

- Aquaculture
- Audit
- Backflow Protection
- Biotoxin
- Cleansing Study
- Education
- Federal Waters
- Foreign Relations
- Growing Area Classification
- Laboratory
- Laboratory Approval
- Male-specific Coliphage
- Model Ordinance Effectiveness
- NSSP Evaluation Steering
  - Growing Area Evaluation
  - Control of Harvest
  - In-field Plant Evaluation
- Patrol
- Proposal Revie
- Regulatory Relations
- Research Guidance
- Research Management
- Resolutions
- Shellfish Restoration
- Shellstock Identification
- Standards
- Study Design Guidance
- Time Temperature
- Training
- Transportation
- Vibrio Management
- *V.p* Illness Response
- *V.v.* Illness Review
- Wet Storage

*Membership forms and Committee sign-up sheets can be downloaded from the ISSC Website.*

# INTERSTATE SHELLFISH SANITATION CONFERENCE

*Thank you*

**209-1 Dawson Road**
**Columbia SC 29223**
**Phone: 803-788-7559**
**Fax: 803-788-7576**
**Email: issc@issc.org**