Minutes

A meeting of the ISSC Executive Board was held in person and virtually in Denver, Colorado.

I. Attendance

Board Members Present

Michael Bott	Chair
Shannon Jenkins	Vice Chair
Keith Skiles	Executive Director
Eric Hickey	Region 1 Regulatory
Lori Howell	Region 1 Industry
Debra Barnes	Region 2 Regulatory
Steve Fleetwood	Region 2 Industry
Danielle Schools	Region 3 Regulatory
Gary Hill	Region 3 Industry
Portia Sapp	Region 4 Regulatory
Barry Hurt	Region 4 Industry
Todd Phillips	Region 6 Regulatory
Miranda Reis	Region 6 Industry (alternate)
Blake Millett	Non-Producing
Jonathan Gerhardt	Non-Producing
Melissa Abbott	FDA
Laurie Farmer	FDA/ORA
Steven Wilson	NOAA
Bill Kramer	EPA
David Fyfe	Northwest Indian Fisheries Commission
Kohl Kanwit	Past Chair
AJ Erskine	VMC Chair
Keith Jackson	Retail Advisory
Kathy Brohawn	Lab Chair

Board Members Absent

Erik Broussard	Region 5 Regulatory
Steve Pollack	Region 5 Industry

Bruce Flippens	Non-Producing
Mike Hughes	CDC

II. Minutes

A request was made to expand on the phrase “no action” used to describe board decisions in the minutes from the previous board meeting.

A consensus was reached to table further discussion of the minutes until later in the meeting when the 2023 summary of actions will be discussed.

III. Introductory Comments

FDA

Staffing updates include Steve Bloodgood moving to the seafood safety division, as well as two vacancies for branch chiefs. Applications for those positions close October 23rd, and links are available on the ISSC website.

The FDA has been testing for PFAS since 2019, from a wide range of foods. Data is limited at this time, but early testing indicates that seafood may be at high risk for PFAS. The FDA is pursuing additional seafood testing, and has plans to collect and analyze clams, mussels, and scallops.

Using NOAA’s landing data, the FDA was able to identify which states had the highest contamination of raw clams, and has asked them to participate in an upcoming study. The FDA plans to reach out to the ISSC executive office with a letter inviting collaboration in the study, and will follow up with a call for interested states.

Questions were raised on what locations would be considered for testing. FDA representatives responded that open areas make the most sense for testing.

Other questions included whether there was available clinical data on the relationship between PFAS and human health. FDA representatives responded that there were some risk assessments available, but since PFAS is an emerging hazard there is not a bevy of information.

The FDA is developing SOP regarding stakeholder concerns for consumer advisories.

The FDA would like to collaborate with fellow ISSC stakeholders about how to best honor the significant anniversary of the NSSP at the next biennial meeting.

There is an upcoming reimagining of the human foods program. The FDA expressed that this is a once in a generation opportunity to increase unification of field work. This project is still in development, and the impact on molluscan shellfish will be limited if at all.

The upcoming shellfish training course offerings for 2024 will be provided to the ISSC executive office.

The FDA extended thanks to the executive office as well as the states who participated in the job task analysis.

NOAA

A National Seafood Strategy was released by NOAA in March of 2023. It prompted the consumption and purchase of seafood.

An aquaculture strategy to develop more aquaculture in the US is in the final stages of development.

The USDA and NOAA have been working to try to encourage the implementation of seafood in children's diets over the next ten to fifteen years. Strategies to achieve this goal include a push for increased awareness of different seafood products available for purchase, and making product forms appealing to children. Any ideas or input into this goal are welcome.

NOAA is in the process of hiring between twenty and thirty seafood safety officers across the country.

EPA

The EPA recently completed a review of the beach act, using human fecal source identifiers

There are procedure changes to how the EPA is dealing with PFAS. They are currently working to develop national recommended guidelines. There is not a lot of good data on the impact of PFAS on molluscan shellfish yet. They are currently focusing on the human health criteria, and aiming to have a draft completed by the Fall of 2024.

IV. Regional Updates

Region 1 Regulatory

New Hampshire has successfully updated their regulations.

Rhode Island faced difficulties when an illness outbreak due to shellfish consumption was confirmed in late July. They are currently developing a vibrio control plan in response.

Maine expressed concerns about the varying formats states are using to share information. With the retirement of shellfish program lead, Jeff Kennedy, Kristin Pennipas is currently filling in.

Massachusetts reported a busy vibrio season with steady cases reported from June into October. In response several full time employees were committed to complete investigations. They have lost two standardized inspectors to retirement and promotion, and are hoping to standardize new inspectors in six to eight months. Their primary concern is FDA advisories on canadian products, and request that the FDA provide clarity.

Region 1 Industry

Heavy rain has provided substantial challenges for the shellfish industry. Climate change is shifting shellfish growing habitats. Across the region there is an increased number of leases and oyster production, while illness numbers remain stable.

There is concern about the amount of press surrounding flesh eating bacteria, and the subsequent suppression of sales. This has been attributed to a press/CDC issue with conflating the number of vibrio wound illnesses with the number of oyster illnesses. A conversation with the CDC is requested on how they discuss wound vs. oyster illnesses going forward.

A motion was made to form a workgroup for the discussion of vibrio risk messaging, documentation and investigation, to include CDC participation. The motion was seconded. Another motion was made to table further discussion of the above motion until the old business section of the meeting. The motion was seconded and carried by a voice vote.

Region 2 Regulatory
New York and Connecticut experienced considerable press coverage associated with VV wound infections and the three reported deaths related to swimming in brackish water. Unrelated to shellfish, but news coverage was misleading. Local industry reported negative impacts as a result.

Connecticut has hired a new shellfish pathologist and is resuming pathology testing. They now have a fully staffed shellfish program.

New York has a new director of marine resources and has just completed one of the largest shellfish restoration projects in the state. They are currently developing a shellfish restoration program, and expect it to be completed next year.

Region 2 Industry
Reports that the product has been good, despite avian issues, and that Connecticut industry has been significantly impacted by press coverage.

Region 3 Regulatory
Delaware reports that all is well in the shellfish program. They are continuing to expand their capabilities and have a new staff member taking over shellfish dealer inspections.

Maryland has submitted a response regarding the unresolved issue, and has yet to get a response from the FDA other than a confirmation of receipt.

Virginia has made several programmatic changes, including the moving of the marina program. Linda Macfarland will be starting in a lab manager position on October 25th, and there are two lab vacancies looking to be filled. Last year extended harvest control into the month of October, but this year it is going smoothly. They have issued a recall due to product being harvested from a closed rainfall conditional area, but have seen no reported illnesses.

Region 3 Industry
Reports that sales have been good, but market sales are down due to the economy and media coverage.

Region 4 Regulatory
Reports that the state of gulf oysters are in bad shape. There was a special meeting held over the summer in order to look for resources and assistance from states regarding restoration strategies.

There is discussion of standardizing metrics regarding fisheries monitoring and success, as many states acknowledge that landing data is reported differently among states.

Preliminary estimates see 34 million in damages from hurricanes, and there is anticipation of a difficult year moving forward.

Florida has added staff in a sampling group to work on pilot sampling to overcome closures.

North Carolina is preparing to reopen one of its labs that was lost in 2014.

Region 4 Industry
Hurricane impacts on industry have been significant in Florida.

A restoration project in Charlotte has led to a lot of good response from younger professionals who connect on water safety and health issues. Restoration may be a way to connect with a new group of people.

Region 6 Regulatory
Washington is currently undergoing a rulemaking debate, the main issues of which are vibrio plant and seed size. The debate has been a collaborative process, and there is still more to do in order to get the right policy in place.

A motion was made to reestablish a regulatory relation committee consisting of participants from each reg region both from the SSCA and industry along with representatives from the FDA. FDA participants determined by the federal agency to include at minimum two regional specialists to meet at least quarterly.

A friendly amendment was made and accepted to include the CDC. The motion was seconded and carried by a voice vote.

A second motion was made to establish an emerging issues committee that includes members from each of the regulatory and industry regions, FDA, CDC, and, on an ad hoc basis, FDA shellfish specialists, SSCA employees, industry members and any subject matter experts that are not permanent members necessary to adequately address the issues being considered by the committee. The emerging issues committee charge shall be consideration of developing or novel issues of concern to ISSC members, either mutually or collectively, to FDA, SSCA, industry, or any other stakeholder group. Additionally past issues brought by a committee member deemed appropriate for consideration by the committee shall also be considered for deliberation. Permanent members shall include a regulatory and an industry member from each region, and FDA, CDC, EPA and NOAA designees.

The motion was seconded. A friendly amendment to add the requirement of quarterly committee meetings to the motion was made and accepted. The motion was carried by a voice vote.

A motion was made to reconsider the original regulatory relations motion, as it was made superfluous by the most recent motion. The motion was seconded and carried by a voice vote.

Motion was made to establish a regulatory relations committee as described in the original motion. The motion was seconded and denied by a voice vote.

Region 6 Industry
Expressed that it becomes challenging when the perception is that the FDA is putting pressure on state authority who in turn place it on industry.

There are three open rules, seed size, BP rules, and fee increases in licensing for shellfish operators. Washington currently has the highest licensing fees in the country, and is statutorily required to be a fee recovery program for shellfish. The fee increases are potentially from $3,400 to $15,000 for the same license.

California has experienced a significant amount of rain resulting in frequent closures that happen for a long period of time and lawsuits against the city as it

has significant impacts to industries ability to operate. Conversations regarding crop insurance are work in progress. Growers are working to compile better inventory systems to track more significantly and accurately.

V. Program Chairman's Report

2025 Biennial Meeting
The biennial meeting scheduled for 2025 is to take place in a non producing state.

There are requests to consider the lower end of the cost structure when evaluating possible locations, as many members pay out of pocket to attend.

There were also requests to look for a hub area with plenty to do within walking distance.

2024 Spring Board Meeting
Request for input regarding hosting the next board meeting as in person, virtual or hybrid. Many would prefer a virtual meeting.

A motion was made to host the spring 2024 board meeting virtual;y only. The motion was seconded and carried by a voice vote.

VI. Executive Committee Report

The ISSC no longer has to reapply for their grant in a five year cycle.

The company hired to complete the 2022 tax return requested and received an extension, and it is currently underway.

The executive office needs to collect financial conflict of interest forms from the board. Comments were made that the form should be more specific, as it is too general currently. A suggestion was made to read an antitrust statement at the start of every board meeting as a substitute for the signed statements.

VII. Committee Reports

The laboratory committee reached a final recommendation for proposal 19-101. The original proposal included changes to chapters 1,3 and 15, and the lab committee felt that the goals of the proposal could be achieved through edits to chapter 3. They introduced new concepts in section three of the chapter. The new text mimics existing text about emergency method adoptions. These guidelines would only be for a facility that wishes to be a lab, or if there is an emergency or new method, and would make no changes for a lab that is already conforming.

Some expressed concerns that the lab committee went beyond the scope of what they were asked to do, and the board voting on this interim measure would be inappropriate.

The lab committee responded that they felt this response was an attempt to address the goals of the proposal while satisfying a number of competing interests.

Options on how to hand the lab committee proposal were put forth, including the board not taking any action on the proposal, and allowing it to go to the next biennial meeting without interim approval. Another option would be, if there was a specific direction the board could give the lab committee as part of the charge, that could be proposed and voted on.

A motion was made for the board to provide interim approval of proposal 19-101 to go back to task force recommendation as accepted at the 2023 biennial meeting. The motion was seconded.

A friendly amendment was made and accepted to add the phrase “conditionally conform to utilize approved methods under emergency conditions.”

A friendly amendment was made and accepted to add the phrase “notwithstanding any other provision relating to conditional conforming status of the NSSP.”

The motion was carried by a voice vote.

After further discussion regarding concerns that the proposal could possibly conflict with the MO, a motion was made to table to the first motion and to reconvene on another call in the next few months to discuss the proposal further.

The motion to reconsider the previous motion was seconded and carried by a voice vote.

The motion to table the original motion was seconded and carried by a voice vote.

VIII. Old Business

2023 Summary of Actions and NSSP Guide Revision
All edits have been made and should be submitted to the FDA within a week.

Draft Minutes
Suggested language to clarify the minutes was proposed: “With regards to proposal 23-104 with the vote taken by the board for no action meant that the board took no action on the recommendation by the FDA to send the proposal back to committee. Because of this the voting delegates decision to adopt the proposal was not changed by the executive board and the new guide will be published as previously approved by the general assembly.

Regarding 23-204 , the distinction was that the FDA was in nonconcurrence with the action taken by the conference because it is the FDA’s position that the adopted language is in direct conflict with the principles of 21 CFR 123, *Seafood HACCP Regulation* and the policy outlined in the Fish and Fishery Products Hazards and Controls Guidance, 4th edition (2022 version) (Hazards Guide).” Since this action will not be published due to being in conflict with federal regulation, it will be reconsidered at the next conference.”

A motion was made to approve minutes as amended. The motion was seconded and approved by a voice vote.

Model Ordinance Vp Control Plan Guidance
Recommendation that the board establish a work group to develop guidance on a Vp work plan as outline in Proposal 07-202.

A motion was made to make a work group to develop model ordinance and Vp control plan guidance that will report its findings to the VMC. The motion was seconded and carried by a voice vote. \

Messaging Regarding Illnesses

Questions were raised on what EPA guidance was available to public regarding vibrio warnings. The EPA responded that such materials exist and have been circulated in the past, and that it may be appropriate to recirculate them with the additional audience of the press.

Comments were made to consider evaluating education efforts to review and develop an implementation plan, and that the appropriate materials be made available to physicians, pharmacies, and the media.

Questions were raised about whether or not there is an appropriate press organization to bring these messaging concerns to, and if the executive office could look into facilitating such a meeting.

The executive office will set up a meeting between the CDC and the concerned stakeholders regarding appropriate messaging regarding Vp illnesses.

IX. New Business

Committee Rosters

Committee rosters have been distributed. Any desired substitutions should be communicated to the executive office via email

A motion was made to adopt the committee rosters. The motion was seconded and carried by a voice vote.

Recall Work Group

The Executive Office is developing a working group to look at both domestic and international recall and develop process flows to assist with efficiency. When finished with development of this proposed group, the executive office will bring it to the board.

FDA Status of the States/ Update on Training and Technical Assistance.

In 2022 7 states requested non-OTED training, and two of these requests are currently outstanding.

6 stats submitted technical requests, four of which have been completed.

Texas requested assistance with the illegal importation of shellfish from Mexico.

In 2023 there were requests from eleven states, all OTED. The FDA encourages states not to hesitate submitting requests. There were two VARB requests in 2023, and six GARB projects in the queue.

X. Other Information

The ISS meeting in 2024 will be held in New Jersey.

Rhode Island has requested updates on the issues with the EU, but was informed that there was no new information.

XI. Adjournment

A motion was made to adjourn the board meeting. The motion was seconded and carried by a voice vote.