ISSC 2019
Committee Report

Committee Name: Laboratory Committee
Committee Chair and Vice-Chair: Stacey Wiggins and Andy Haines
Meeting Dates: Multiple Conference Calls 2018-2019 and In-Person Meeting October 6, 2019

Committee Members:

Stacey Wiggins	**Andy Haines**	Jennifer McDonald
(Chair)	(Vice-Chair)	**Dana Dvoracek-Driksna**
Joseph DeCrescenzo	**Matthew Forester**	**Shelley Lankford**
Jill MacLeod	**Linda McFarland**	**Diane Regan**
Lee Porter	Wade Rourke	**Richard Burrow**
Gina Olson	Drew Sheehan	**Joel Hansel**
Lizzie Farrell	**Shannara Lynn**	(EPA Delegate)
(FDA Delegate)	(NOAA Delegate)	**Cheryl Lassitter**
Linda Chandler	**Jessica Jones**	(NOAA Advisor)
(FDA Advisor)	(FDA Advisor)	**Johnna Fay**
Quay Dortch	**Maggie Broadwater**	(FDA Advisor)
(NOAA Advisor)	(NOAA Advisor)	

Charges

Charge 1: Proposal 13-111: DSP PPIA Kit for Determination of Okadaic Acid Toxins Group (OA, DTX1, DTX2) in Molluscan Shellfish

Findings/Conclusions: The Laboratory Committee has reviewed previous data packages and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 2: Proposal 13-114: Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination

Findings/Conclusions: The Laboratory Committee has reviewed previous data packages and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 3: Proposal 15-109: PSP HPLC-PCOX Species Expansion

Findings/Conclusions: The Laboratory Committee has reviewed a previous data package and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 4: Proposal 15-112: Direct Plating Method for trh

Findings/Conclusions: The Laboratory Committee has reviewed a previous data package and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 5: Proposal 15-114: Male-Specific Coliphage Enumeration in Wastewater by Direct Double-Agar Overlay Method

Findings/Conclusions: The Laboratory Committee has reviewed a previous data package and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 6: Proposal 17-103: Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Method for the Determination of Diarrhetic Shellfish Poisoning (DSP) Toxins in Shellfish

Findings/Conclusions: The Laboratory Committee has reviewed a previous, limited data package for mussels and oysters and has requested outstanding data and information before review and recommendation of the method can be completed for those species.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 7: Proposal 17-106: Matrix Expansion for the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination to Allow Use with Geoduck

Findings/Conclusions: The Laboratory Committee has reviewed a previous data package and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee has recommended that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 8: Proposal 17-108: Detection of ASP biotoxins in *Mytilus edulis* (Blue Mussel) shellfish by ELISA for Domoic Acid

Findings/Conclusions: The Laboratory Committee has reviewed a previous data package and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 9: Proposal 17-110: Alkaline Phosphatase Probe Method for *Vibrio vulnificus* and *Vibrio parahaemolyticus* Detection in Oysters – Laboratory Evaluation Checklist

Findings/Conclusions: The Checklist Subcommittee has reviewed the revised checklist and recommended that the Laboratory Committee adopt the checklist as submitted. However, at the Laboratory Committee level there were too many suggested amendments to consider during the limited Committee timeslot at the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 10: Proposal 19-101: Conditionally Conforming Laboratory Status

Findings/Conclusions: The FDA stated that they would not be able to support the proposal even if it were adopted by the Conference as it is in opposition to current regulation. Further, the Laboratory Committee submitted proposal 19-301 to address the need for ensuring that laboratory evaluation checklists are submitted along with method applications.

Recommendation: The Laboratory Committee recommends that Task Force I take no action on this proposal.

Charge 11: Proposal 19-126: MPN-Real-Time PCR for Enumeration of *Vibrio vulnificus* in Oysters

Findings/Conclusions: The Laboratory Committee found that the single laboratory validation data package supported adoption of the MPN-Real-Time PCR method for the enumeration of *Vibrio vulnificus*.

Recommendation: The Laboratory Committee recommends that Task Force I adopt the proposal as submitted.

Charge 12: Proposal 19-127: Modifications of the MARBIONC Brevetoxin ELISA Standard Operating Procedures

Findings/Conclusions: The Laboratory Committee reviewed the original proposal and requested additional information from the submitter. The submitter then provided a revised proposal package which the Laboratory Committee found to fully address the outstanding questions. . This proposal and proposal 19-143 are related as 19-127 is the method and 19-143 is the laboratory evaluation checklist for this method.

Recommendation: The Laboratory Committee recommends that Task Force I adopt the proposal as amended by the submitter.

Charge 13: Proposal 19-128: Laboratory Method for *Vibrio parahaemolyticus* and *Vibrio vulnificus* Enumeration and Detection Through MPN and Real-Time PCR

Findings/Conclusions: The Laboratory Committee has reviewed the proposal data package and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 14: Proposal 19-129: Micropipettor Verification

Findings/Conclusions: The majority of the Laboratory Committee thought that the existing language regarding micropipettor calibration in laboratory evaluation checklists is needed.

Recommendation: The Laboratory Committee recommends that Task Force I take no action on this proposal.

Charge 15: Proposal 19-130: Microbiology Laboratory Evaluation Checklist – Standards Thermometer

Findings/Conclusions: This proposal removes a specific reference to mercury-in-glass thermometers because there are now suitable alternatives available.

Recommendation: The Laboratory Committee recommends that Task Force I adopt this proposal as submitted.

Charge 16: Proposal 19-131: NSSP Microbiology Laboratory Evaluation Checklist – Reagent Water Quality

Findings/Conclusions: There were potential amendments that warranted discussion beyond the limited timeframe for the Committee deliberation at the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 17: Proposal 19-132: Microbiology Laboratory Evaluation Checklist – Working Thermometers

Findings/Conclusions: There were potential amendments that warranted discussion beyond the limited timeframe for the Committee deliberation at the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 18: Proposal 19-133: Microbiology & PCR Laboratory Evaluation Checklists – Working Thermometers

Findings/Conclusions: There were potential amendments that warranted discussion beyond the limited timeframe for the Committee deliberation at the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 19: Proposal 19-134: Membrane Filtration Technique for Seawater using mEndo Agar LES Checklist

Findings/Conclusions: This proposal covered the same topic, an mEndo laboratory evaluation checklists, as proposal 19-137.

Recommendation: The Laboratory Committee recommends that Task Force I take no action on this proposal since it is covered by proposal 19-137.

Charge 20: Proposal 19-135: Microbiology Laboratory Evaluation Checklist - Sterilization

Findings/Conclusions: The original proposal seeks to modify a checklist item relating to autoclave sterilization temperature range. The Laboratory Committee further amended the language within this checklist item relating to the types of thermometers that can be used to monitor autoclave temperature.

Recommendation: The Laboratory Committee recommends that Task Force I adopt this proposal as amended.

Charge 21: Proposal 19-136: NSSP DSP Laboratory Evaluation Checklist

Findings/Conclusions: There were too many potential amendments that warranted further discussion, including those by the method submitter, to properly consider during limited timeframe for the Committee deliberation at the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 22: Proposal 19-137: Checklist for the Bacteriological Analysis of UV Treated Process Water Samples by Membrane Filtration (MF) using mEndo Agar LES

Findings/Conclusions: The proposed mEndo laboratory evaluation checklist was amended by the Checklist Subcommittee, who then recommended that the Laboratory Committee adopt as amended. This proposal covers the same material presented in proposal 19-134.

Recommendation: The Laboratory Committee recommends that Task Force I adopt the proposal as amended.

Charge 23: Proposal 19-138: NSSP Microbiology Laboratory Evaluation Checklist

Findings/Conclusions: There were too many potential amendments that warranted discussion beyond the limited timeslot of the Committee deliberation during the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 24: Proposal 19-139: NSSP Microbiology Laboratory Evaluation Checklist

Findings/Conclusions: The proposal modifies the options available for checking the accuracy of working thermometersand provides the optionto use clean gloves during shucking for sample preparation. The proposal was submitted by the FDA and State Laboratory Evaluation Officers.

Recommendation: The Laboratory Committee recommends that Task Force I adopt the proposal as submitted.

Charge 25: Proposal 19-140: NSSP Microbiology Laboratory Evaluation Checklist

Findings/Conclusions: There were too many potential amendments that warranted discussions beyond the limited timeframe of the Committee deliberation at the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 26: Proposal 19-141: NSSP Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP) Laboratory Evaluation Checklist

Findings/Conclusions: There were too many potential amendments that warranted discussions beyond the limited timeframe of the Committee deliberation at the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force I refer to an appropriate Committee as determined by the Conference Chair.

Charge 27: Proposal 19-142: Add the use of a mechanical shaker to the water microbiology methods checklist in the sample preparation requirements section and include a reference

Findings/Conclusions: The proposal adds the use of a mechanical shaker to the water microbiology checklist. The Laboratory Committee made amendments at add some flexibility to the time constraints by adding "at least" in front of the time requirement.

Recommendation: The Laboratory Committee recommends that Task Force I adopt this proposal as amended.

Charge 28: Proposal 19-143: MARBIONC Brevetoxin (Neurotoxic Shellfish Poisoning; NSP) ELISA Method Laboratory Evaluation Checklist

Findings/Conclusions: This new checklist for the MARBIONC ELISA was amended by the Laboratory Committee to address concerns related to the incubation step requirements and to make it consistent with the method procedure. This proposal is related to proposal 19-127, where 19-127 is the method and 19-143 is the laboratory evaluation checklist for the method.

Recommendation: The Laboratory Committee recommends that Task Force I adopt this proposal as amended.

Charge 29: Proposal 19-146: Micropipettor Verification

Findings/Conclusions: The majority of the Laboratory Committee thought that the existing language regarding micropipettor calibration in laboratory evaluation checklists is needed.

Recommendation: The Laboratory Committee recommends that Task Force I take no action on this proposal.

Charge 30: Proposal 19-150: Neogen's 'Reveal 2.0 for PSP' for detection of PSP

Findings/Conclusions: The Laboratory Committee has reviewed previous data packages and has requested outstanding data and information before review and recommendation of the method can be completed.

Recommendation: The Laboratory Committee recommends that Task Force refer to an appropriate Committee.