ISSC 2023
Committee Report

Committee Name: Supplemental Lab Data Requirements
Committee Chair: Andy Haines
Meeting Dates: January 27th and February 13th, 2023

Committee Members:

Andy Haines (Chair)	Scott Berbells
Nyle Taylor	Joseph DeCrescenzo
Kirk Wiles	Johnna Fay (FDA Delegate)
Bob Schuster	Gina Olson (FDA Advisor)
Jill Fleiger	Quentin Forrest (FDA Advisor)
Vanessa Zubkousky-White	Jessica Jones (FDA Advisor)
Chris Nash	Joel Hansel (EPA)
Linda McFarland	Tricia Rabideau (NOAA)

Charges

Charge 1: Proposal 19-105: Laboratory approval for sample analysis with no Model Ordinance defined method or action level

Findings/Conclusions: The Committee met twice via WebEx to discuss the original rationale and goals of the proposal, and to discuss potential alternative language that might achieve those goals while at the same time addressing some of the concerns with the original proposal that were expressed at the 2019 biennial meeting. Through discussion, the Committee developed amendments to the original proposal language that help to more clearly define when non-evaluated laboratories can be used to generate data to support regulatory decisions. The amended language also provides better direction to Model Ordinance requirements for when and how non-Approved/Approved Limited Use methods can be used.

Recommendation:

The Committee recommends the adoption of Proposal 19-105 as amended.

Chapter III. @.01 – Quality Assurance

A. NSSP Conformance Required for all laboratories supporting the NSSP. For any toxin, pathogen, bacteria, virus, or other contaminant for which there is an action level specified in the NSSP and an Approved NSSP Method or Approved Limited Use Method of detection, ~~A~~all laboratory analyses ~~for compliance with classification requirements that require a specific method, actions level, and use defined in the Model Ordinance~~ generating data to support regulatory decisions shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under ~~the NSSP~~ Chapter I @.03 B. 1.

(1) If there is a toxin, pathogen, bacteria, virus, or other contaminant for which the NSSP has no Approved NSSP Method or Approved Limited Use Method, the Authority may use a non-evaluated laboratory to generate data utilizing the best science available. In these circumstances, the Authority shall follow the procedures and guidelines defined in Chapter III @.02 Methods.

(2) Shellfish growing area closures may be made using data generated in non-evaluated laboratories.