ISSC 2019
Committee Report

Committee Name : Federal Waters Subcommittee
Chairperson: Joel Hansel
Date of Meeting: September 25, 2019

Committee Members Present:

Joel Hansel (Chairperson)	Stacey McLeroy (FDA Advisor)	(FDA Advisor)
Kohl Kanwit	David Wiggins	Angela Ruple (NOAA Delegate)
Kirk Wiles	(FDA Advisor)	Jon Bell
Mike Hickey	Pete Koufopoulos	(NOAA Advisor)
Keith Skiles	(FDA Advisor)	Steven Wilson
Eric Hickey	Melissa Abbott	(NOAA Advisor)
Quentin Forrest (FDA Delegate)	(FDA Advisor) Raymond Burditt	Laurice Churchill (NOAA Advisor)

Charges

Charge 1: Proposal 17-116: Sanitary Control of Molluscan Shellfish Harvested From Federal Waters
The committee is requested to review Proposal 17-116 as adopted and recommend modifications as appropriate. Modifications could include additions or deletions to the existing language for the purposes of addressing public health concerns in shellfish harvesting areas in federal waters

Findings/Conclusions:

Following the 2017 Biennial Meeting, there was an attempt to implement the adopted language in 17-119. Following discussions with FDA, it became apparent that additional regulatory infrastructure was necessary to incorporate shellfish from Federal Waters with biotoxin concerns into the NSSP. In Proposal 17-116, the FDA requested the appointment of a committee to provide assistance to FDA in addressing aquaculture in Federal Waters. This committee charge was expanded to include the harvesting of shellfish from Federal Waters with biotoxin concerns including aquaculture and wild harvest. A Subcommittee was appointed which included FDA, NOAA, EPA and Northeastern states with biotoxin and Federal Waters expertise. This Subcommittee met in College Park in October of 2018 and discussed needed changes to the NSSP to incorporate Federal Waters into the NSSP.

Recommendations:

1. The Subcommittee submitted the following proposals:

- 19-202
- 19-203
- 19-214
- 19-223
- 19-228
- 19-229

2. The Subcommittee also reviewed and recommends the adoption of Proposal 19-120.

3. The Subcommittee developed the following action list for the implementation of Federal Waters.

1. Gather more information regarding NOAA funded state patrol activities in federal waters.
   Responsible Party(s): States of New Jersey and Maine/NOAA
   Timeline for Completion:
   Status: Maine and New Jersey have joint enforcement agreements with NOAA that could be used to address patrol in federal waters other states may have this agreement as well

2. Develop Model Ordinance language needed to clarify FDA roles and responsibilities in providing federal oversight. FDA has indicated that any reference to FDA as the Authority creates legal implications for the FDA.
   Responsible Party(s): Federal Waters Subcommittee
   Timeline for Completion:
   Status: Proposal 19-203 was submitted

3. **Determine how dealer certification oversight will need to be addressed in agreements or contracts between state and federal agencies providing oversight.
   Responsible Party(s): Federal Waters Subcommittee
   Timeline for Completion:
   Status: Proposals 19-223, 19-228 and 19-229 were submitted

4. **NOAA will determine appropriate controls for issuing harvesting permits in federal waters to address:
   a. Differentiation between harvesting in waters where shellfish are prone to biotoxin accumulation and waters without biotoxin concerns
   b. Classification designation for federal waters prone to biotoxin accumulation; and
   c. Harvester Training
   Responsible Party(s): NOAA
   Timeline for Completion:
   Status: Pending
   Proposal 19-214 addresses harvesting requirements

5. FDA and NOAA will determine how best to collectively address the required prerequisites in Chapter I .01 A-E.
   Responsible Party(s): FDA/NOAA
   Timeline for Completion:
   Status: Pending

6. FDA and NOAA will discuss the possibility of NOAA performing oversight of program elements with FDA evaluating NOAA oversight.
   Responsible Party(s): FDA/NOAA
   Timeline for Completion:
   Status: Pending

7. FDA and NOAA will determine how best to address V.p. and V.v assessments for wild harvest.

Responsible Party(s): FDA/NOAA
Timeline for Completion:
Status: Pending

8. NOAA will determine how to include shellfish production reporting as a condition for harvester permit.

   Responsible Party(s): NOAA
   Timeline for Completion:
   Status: Pending

9. **FDA will review current biotoxin data for the purposes of defining the threshold conditions that would constitute "where toxin producing phytoplankton are known to occur and toxins prone to accumulate in shellfish."

   Responsible Party(s): FDA
   Timeline for Completion:
   Status: The FDA is developing a GIS database of toxic phytoplankton and toxins in shellfish detected in federal waters. The current database includes the presence of: (1) paralytic shellfish poisoning (PSP) toxins on Georges Bank and federal waters off the northeast coast of the United States, (2) PSP and amnesic shellfish poisoning (ASP) toxins in federal waters off the coast of California, and (3) *Karenia brevis* concentrations and neurotoxic shellfish poisoning (NSP) toxins in the Gulf of Mexico. The GIS database is only available within FDA at this time; therefore, database information will be shared outside of the FDA through screenshots and other created biotoxin maps based on the information in the database. The FDA will continue to update the database as scientific information becomes available (i.e., this will be a living resource).

10. **FDA will continue to develop biotoxin mapping tools with refined temporal and spatial patterns of marine biotoxin hazards in federal waters to establish designation which could be communicated to persons harvesting in federal waters

    Responsible Party(s): FDA
    Timeline for Completion:
    Status: While the GIS database in #9 serves as the scientific support for where toxic phytoplankton and toxins in shellfish are known, this resource will serve as the documentation of their presence to industry and states. This tool can then be used to inform aquaculture siting and/or determining where biotoxin control is required for both wild harvest and aquaculture in federal waters. The current action item is for the FDA to create the biotoxin maps external to GIS for sharing with stakeholders for the data gathered to date (as described above). This resource will be updated as the scientific database expands.

11. **ISSC and FDA will develop guidance to states regarding an implementation strategy for new -requirements adopted in Proposal 17-119.

    Responsible Party(s): Peter Koufopoulos/Ken Moore
    Timeline for Completion:
    Status: FDA has communicated an implementation strategy but until #4 is addressed, implementation is unlikely to occur