

**ISSC 2013 Biennial Meeting
January 25 – January 31, 2014 – San Antonio, Texas
Committee Report**

Committee Name : Laboratory Methods Review & Quality Assurance
Chairperson: Patti Fowler
Date of Meeting: 01/27/14
Recorder: Jessica Jones
Approved By: Patti Fowler

Committee Members Present:

Patti Fowler	Richard Burrow	Darcie Couture
Carol Dorsey	Matthew Forrester	Tom Howell
Leonora Porter	Valerie Wunderly	Stacey DeGrasse
Melissa Evans	Jessica Jones	Steve Plakas
Cheryl Lassitter	Joel Hansel	Linda Chandler

Committee Members Absent:

Gregg Langlois	Brian Hiatt	John Schwartz
Paula Scott	Jeff Van de Riet	Dave Wallace

Charges

Charge 1: 05-111: Rapid Extraction Method for PSP and ASP

Findings:

Additional information that was asked for was not provided by submitter.

Conclusions:

LMRC is unable to recommend this proposal due to lack of data.

Recommendations:

Recommend Task Force take No Action because this proposal is resolved by action on proposal 13-109.

Charge 2: 05-115: Thermazyme™ ACP Test for Use on Thermally Processed Shellfish Products

Findings:

Additional information that was asked for was not provided by submitter

Conclusions:

LMRC is unable to recommend this proposal due to lack of data.

Recommendations:

Recommend Task Force take No Action-Insufficient data to determine if the method is fit for purpose within the NSSP

Charge 3: 09-105: Quantitative Immunoassay for the Detection of Domoic Acid Test

Findings:

Additional information that was asked for was not provided by submitter.

Conclusions:

LMRC is unable to recommend this proposal due to lack of data.

Recommendations:

- 1) Recommend Task Force take No Action-Insufficient data to determine if the method is fit for purpose within the NSSP
- 2) Minority report attached with recommendation for Task Force to refer to appropriate committee as determined by the Conference chairman

Charge 4: 09-107: Saxitoxin (PSP) ELISA Kit

Findings:

Additional information that was asked for was not provided by submitter.

Conclusions:

LMRC is unable to recommend this proposal due to lack of data.

Recommendations:

Recommend Task Force take No Action because this proposal is resolved by action on proposal 13-109

Charge 5: The Conference adopted action levels associated with Neurotoxic Shellfish Poisoning toxins. Presently the Conference has not adopted approved methods for these toxins. The Committee is requested to recommend methods should sampling be necessary.

Findings:

LMRC has determined that the original intent was for DSP, not NSP

Conclusions:

LMRC has considered proposals for DSP methods. Additionally, LMRC believes that without an approved method, any method could be used on an emergency basis.

Recommendations:

No Task Force recommendation on this charge

Charge 6: 11-107: Reveal ASP (Domoic Acid) Test Kit

Findings:

Additional information that was asked for was not provided by submitter

Conclusions:

LMRC is unable to recommend this proposal due to lack of data

Recommendations:

Recommend Task Force take No Action because this proposal is resolved by action on proposal 13-112

Charge 7: 11-108: Update Microbiology Laboratory Evaluation Checklist

Findings:

A microbiological checklist is necessary for the Conference, however, this proposal still has some issues.

Conclusions:

Further work on the proposal is necessary in order for an appropriate checklist to be developed.

Recommendations:

Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman

Charge 8: 11-109: Update PSP Laboratory Evaluation Checklist

Findings:

A PSP checklist is necessary for the Conference, however, this proposal still has some issues

Conclusions:

Further work on the proposal is necessary in order for an appropriate checklist to be developed

Recommendations:

Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman

Charge 9: Review the SLV protocol for acceptance of a new method for compliance with quality assurance requirements (Specifically when a developer of a newly accepted method by the ISSC is required to submit a checklist for the method to the Laboratory Quality Assurance Committee for review).

Findings:

LMRC finds no issues with this at this point in time

Conclusions:

None

Recommendations:

No recommendations

Charge 10: Review specific reported problems associated with Laboratory Quality Assurance.

Findings:

No problems noted

Conclusions:

Recommendations:

No recommendations

**Charge 11: 13-100: ASP ELISA for Determination of Domoic Acid in Molluscan Shellfish
(Hans Kleivdal)**

Findings:

The application for the method, as submitted, was incomplete. Additionally, there were serious faults with the information submitted. Finally, this is identical proposal as one submitted in 2009.

Conclusions:

The method, as submitted, is not acceptable and it is unlikely to be corrected in the near future given the previous submittal.

Recommendations:

Recommend Task Force take No Action-Insufficient data to determine if the method is fit for purpose within the NSSP

**Charge 12: 13-109: Expanding the Use of the Abraxis Shipboard ELISA for the
Determination of Paralytic Shellfish Poisoning (PSP) Toxins**

Findings:

There is a need for the expanded use of this method and this is currently being addressed by FDA

Conclusions:

There is need for additional data for this proposal prior to full consideration by the LMRC

Recommendations:

Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman

Charge 13: 13-110: Immunoassay Method for Detection of Saxitoxin (PSP) from Shellfish

Findings:

There is a need for this method within the Conference

Conclusions:

Additional data and deliberation is needed before determining acceptability and fit for purpose

Recommendations:

- 1) Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman
- 2) Direct the Executive Office send a letter to the submitter requesting additional information as provided by the LMRC

**Charge 14: 13-111: DSP PPIA Kit for Determination of Okadaic Acid Toxons Group
(OA,DTX1, DTX2) in Molluscan Shellfish**

Findings:

There is a need for this method within the Conference

Conclusions:

Additional data and deliberation is needed before determining acceptability and fit for purpose

Recommendations:

- 1) Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman

2) Direct the Executive Office send a letter to the submitter requesting additional information as provided by the LMRC

Charge 15: 13-112: Reveal 2.0 ASP

Findings:

There is a need for this method within the Conference

Conclusions:

There is sufficient data to conclude that this method is acceptable for limited use within the NSSP

Recommendations:

- 1) Recommend Task Force adopt this method as a Limited Use Method for the purpose of screening and precautionary closure for ASP
- 2) Direct the Executive Office send a letter to the submitter requesting additional information as provided by the LMRC

Charge 16: 13-113: Reveal 2.0 DSP

Findings:

There is a need for this method by the Conference

Conclusions:

Additional information is necessary before this method can be accepted by the Conference

Recommendations:

Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman and await data to determine fit for purpose

Charge 17: 13-114: Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination

Findings:

There is a need for this method by the Conference

Conclusions:

There was sufficient data to approve this method for certain species and not for others

Recommendations:

- 1) Recommend Task Force approve this method as an alternative to the mouse bioassay for PSP in mussels
- 2) Recommend Task Force approve this method for Limited Use for clams and scallops for the purpose of screening and precautionary closure for PSP
- 3) Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman in order address this method in oysters
- 4) Request Executive Office send a letter to submitter to request a checklist for evaluation of labs using this method with said checklist to be submitted within 3 months

Charge 18: 13-115: PSP HPLC-PCOX Method Evaluation Checklist

Findings:

This checklist is needed to effectively implement a previously adopted method

Conclusions:

There is a need to fully review this checklist for regulatory compliance

Recommendations:

Recommend Task Force refer this proposal to the appropriate committee as determined by the Conference chairman

Charge 19: 13-120-L: Male Specific Coliphage Method for Quahogs (*M. mercenaria*)

Findings:

There is a need for this method in the Conference

Conclusions:

There is sufficient data for this method

Recommendations:

Recommend Task Force adopt this method for use in detecting MSC in hard clams and direct the Executive Office to amend the table at Section IV. Chapter 2 @.11 to add Quahogs to footnote #1

Additional Information:

LMRC directs the ISSC Executive Office to write a letter, in consultation with the LMRC, to member Shellfish Control Authorities concerning the archiving of appropriate samples in order to facilitate validation of methods, specifically those in Proposal 13-112 and 13-113.