Proposal Subject Rapid Screening Method for PSP

Specific NSSP Guide Reference NSSP Guidance Documents, Chapter II;
ISSC Constitution Bylaws and Procedures, Procedure XVI. Procedure for Acceptance and Approval of Analytical Methods for the NSSP; and
Model Ordinance Chapter III. Laboratory @. 02 Methods. C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be: (1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins;

Text of Proposal/ Requested Action

For many years, there has been an expression of need by regulatory agencies and industry to develop a non-animal PSP test to monitor PSP levels with precision and accuracy.

The method developed by Jellett Rapid Testing Ltd has been presented to the ISSC and other regulatory bodies over the past several years. In cooperation with individuals, governments and those organizations, the analytical method has been refined and improved. The Rapid Test kits have been tested in several states and foreign countries, and independent papers have been published attesting to the validity, reproducibility and reliability of these test kits.

The Constitution, Bylaws and Procedures of the Interstate Shellfish Sanitation Conference allows the ISSC, through the Laboratory Methods Review Committee, to accept analytical methods that are sufficiently validated but are not AOAC or APHA methods. This is defined in the Constitution, Procedure XVI. Procedure for Acceptance and Approval of Analytical Methods for the NSSP. Two possible reasons for considering a method are found in Subdivisions i and ii.

Subdivision i. *Meets immediate or continuing need;*
Subdivision ii. *Improves analytical capability under the NSSP as an alternative to other approved or accepted method(s)*

The need for alternative methods has been expressed by regulatory agencies, governmental organizations and industry for many years. The Jellett Rapid Test for PSP has been validated extensively to demonstrate its simplicity, reliability, precision and accuracy. As a result of ongoing improvements and demonstrations of efficacy, and the need that has been expressed by industry and state agencies, the Jellett Rapid Test for PSP is presented as a screening method for the NSSP as a Type III or Type IV method.

Please see attached list of supporting information.

Suggested wording:

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
   (1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins;
   (2) The Jellett Rapid Test for PSP may be used as a screening method for PSP toxins by regulatory and industry laboratories.

Public Health Significance

Currently, only data from certified laboratories conducting PSP analyses using the Mouse Bioassay (MBA) are considered reliable and acceptable. Because of many significant constraints, in practical terms, this means that only state laboratories (in the US, governmental laboratories in other countries) can provide acceptable data at this time. However, acceptance of the Jellett Rapid Test for PSP would allow harvesters, processors, and regulatory agencies to screen for PSP with an accepted method that provides valid useable data.

The Jellett Rapid Test for PSP was developed over several years in answer to the oft-stated need for a rapid, reliable, non-animal analytical method that could be used to supplement the Mouse Bioassay.

Possible applications for The Jellett Rapid Test for PSP include:

- as a method of screening out negative samples in shellfish regulatory labs;
- as a harvest management tool at aquaculture facilities or in wild shellfish harvest areas (especially near shore areas) to determine if shellfish are free of PSP and safe to harvest;
- as a quality control tool for shellfish processing plants, distributors and wholesalers to ensure incoming shellfish are free of PSP toxins before processing or further distribution (this test could become part of the plant's HACCP program);
- as a tool for water classification for biotoxins;
- to assist in site selection for aquaculture activity;
- as a screening tool for toxic phytoplankton in seawater to provide an early warning for shellfish growers; and
- as a research tool for broad scale ecological monitoring.
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The rationale for using the Jellett Rapid Test for PSP is that the kits provide a cost-effective screen (especially in low-volume laboratories) for PSP that can substantially reduce the need for live animal testing and the attendant care and disposal considerations. As a harvest management tool, the use of the Jellett Rapid Test for PSP will supplement regulatory agency efforts and help prevent the harvest of contaminated product. Having the ability to conduct tests using an accepted method will allow those processors who choose to use this test to demonstrate that they are truly controlling for PSP hazards in the harvested shellfish.

A simple, rapid, effective, reliable test, available to all harvesters, regulators, and processors, would increase the monitoring and reduce the chance that shellfish containing PSP toxins above the regulatory limit would be harvested or marketed.

Cost Information (if available)

Each test kit costs $20. It has been reported that each analysis using the Mouse Bioassay costs approximately the same for a large-volume laboratory, but substantially more for small-volume laboratories. However, the costs cited do not take into account the costs associated with maintaining animal care facilities, proper disposal of the test animals, and the dangers associated with injecting live hand-held animals with toxic materials. In the worst case, it is no more expensive than the Mouse Bioassay.

Action by 2003 Lab Methods Review and Lab QA Committees

Recommended adoption as a Type IV method with the following restrictions:

i. Method can be used to determine when to perform a mouse bioassay in a previously closed area.
ii. A negative result can be substituted for a mouse bioassay to maintain an area in the open status.

Recommended the Executive Board charge the appropriate committee with reexamination of this method at the 2005 Conference.

Recommended modifying Guidance Document Chapter II Growing Areas Table A. 10. Type III and Type IV Marine Biotoxin Methods as follows: Insert Type IV under other for Growing Area Survey & Classification, shellfish with the following footnote: The Jellett Rapid Test for PSP.

Action by 2003 Task Force I

Recommended adoption of Proposal 03-116 as amended by the Laboratory Methods Review Committee and Lab Quality Assurance Committee, with the addition of: **iii. A positive result can be used for a precautionary closure.;** and Lab Quality Assurance Committee including the checklist

Action by 2003 General Assembly

Adopted recommendations of 2003 Task Force I.

Action by USFDA

Concurred with Conference action with the following comments:

FDA concurs with adoption of Proposal 03-116 to accept the Jellett rapid PSP test as a tool for states to use in the control of PSP in shellfish. However, several important caveats placed

on use of the Jellett rapid PSP test were not clearly stated in the Summary of Actions. They are:

1. Use of the Jellett PSP test must be based on the currently approved procedure for PSP toxin extraction. No other extraction procedures have been validated and approved for use under the NSSP, including those provided by Jellett Rapid Testing Ltd.

When employing only the Jellett rapid PSP test to screen for saxitoxins, the Shellfish Authority shall make precautionary closures when positive results occur.

Action by ISSC Executive Board Concurred with USFDA

Action by 2005 Laboratory Methods Review Committee Recommended no action on Proposal 03-116.

Rationale – This proposal is adequately addressed in Proposal 05-110.

Action by 2005 Task Force I Recommended adoption of the Laboratory Methods Review Committee recommendation of no action on Proposal 03-116.

Rationale – This proposal is adequately addressed in Proposal 05-110.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force I.

Action by USFDA Concurred with Conference action.

List of attachments

1. Revised submission text
2. FSA report
3. Mackintosh et al. 2002
4. Mackintosh and Smith 2002
5. Jellett et al. 2002a (Toxicon)
6. Jellett et al. 2002b (CWHMA)
7. Vale and Sampayo 2002
8. Silva et al. 2002
9. Rafuse et al. 2002
10. Rafuse et al. in press
11. Laycock et al. 2000
12. Cembella et al. 2002
13. Truman et al. unpublished
14. Instruction sheets from Jellett Rapid Test kits
15. Feedback from Rapid Test users

References for List of Attachments (numbers correspond)

2. FSA Project Code: B04006
FSA Project Title: Assessment and validation of a commercial rapid qualitative assay (MIST Alert™) for detection of amnesic and paralytic shellfish poisons in the UK monitoring programme and as an end-product test

3. Mackintosh, Fiona H., Susan Gallacher, Aileen M. Shanks and Elizabeth A. Smith 2002. Assessment of MIST Alert™, a Commercial Qualitative Assay for Detection of Paralytic Shellfish Poisoning Toxins in Bivalve Molluscs. Journal of AOAC International Vol. 85, No. 3: 632-641.

4. Mackintosh F.H. and E. A. Smith 2002. Evaluation of Mist Alert™ Rapid Test Kits For The Detection of Paralytic and Amnesic Shellfish poisoning Toxins in Shellfish. Journal of Shellfish Research, Vol. 21, No. 2: 455-460.

5. Jellett, Joanne F., Raymond L. Roberts, Maurice V. Laycock, Michael A. Quilliam, Richard E. Barrett. 2002. Detection of paralytic shellfish poisoning (PSP) toxins in shellfish tissue using MIST Alert™, a new rapid test, in parallel with the regulatory AOAC® mouse bioassay. Toxicon 40: 1407-1425

6. Jellett, J.F., Laycock, M.V., Belland, E.R., Bishop, P.C., Thériault, B.L., Roberts, R.L., Quilliam, M.A. and Cembella, A.D. 2001. Rapid toxin tests: MIST Alert™ for PSP and ASP. In: Proceedings of the 7th Canadian Workshop on Harmful Marine Algae. Edited by J.N.C. Whyte. Can. Tech. Rep. Fish. Aquat. Sci. 2386: 23-25.

7. Vale, Paulo, Maria Antónia de M. Sampayo. 2002. Evaluation of extraction methods for analysis of domoic acid in naturally contaminated shellfish from Portugal. Harmful Algae 1: 127-135.

8. Silva, M.A., Jellett, J.F., Laycock, M.V., Quilliam, M.A. and Cembella, A.D. 2001. Phytoplankton monitoring using a rapid field test: MIST Alert™ for Paralytic Shellfish Poisons. In: Proceedings of the 7th Canadian Workshop on Harmful Marine Algae. Edited by J.N.C. Whyte. Can. Tech. Rep. Fish. Aquat. Sci. 2386: 28-34.

9. Rafuse, Cheryl, Allan Cembella, Maurice Laycock, Joanne Jellett. 2001. Rapid Monitoring of Toxic Phytoplankton and Zooplankton with a Lateral-Flow Immunochromatographic Assay for ASP and PSP Toxins. In: Steidinger, K. (Ed) Proceedings of the 10th International Conference on Harmful Algal Blooms St. Petersburg, Florida. Oct 21-25, 2002. Intergov. Oceanogr. Comm., Paris, in press.

10. Rafuse C., M.A. Silva, J.F. Jellett, and A.D. Cembella. 2001. Rapid Monitoring of Toxic Phytoplankton Using the MIST Alert™ for ASP and PSP Toxins at Aquaculture Sites in Atlantic Canada. Aquanet Forum. Dalhousie University Aug. 22, 2001.

11. Laycock, M.V., Jellett, J.F, Belland, Elizabeth R, Bishop, Pamela C., Thériault, Brigitte L, Russell-Tattrie, Audra L. Quilliam, Michael A, Cembella, Allen D, Richards, Robert C. 2001.MIST Alert™: A Rapid Assay for Paralytic Shellfish Poisoning Toxins. Proceedings of the 9th International Conference on Harmful Algal Blooms, Hobart, Australia, 7-11 February 2000, Hallegraeff, G.M., Blackburn, S.I., Bolch, L.J., Lewis, R.J. (Eds.) IOC of UNESCO, 2001.

12. Cembella, A. D., M. A. Quilliam, N. I. Lewis, A. G. Bauder, C. Dell'Aversano, K. Thomas, J. Jellett and R. R. Cusack. 2002. The toxigenic marine dinoflagellate *Alexandrium tamarense* as the probable cause of mortality of caged salmon in Nova Scotia. Harmful Algae, Volume 1, Issue 3: 313-325.