Proposal Subject Rapid Screening Method for PSP

Specific NSSP Guide Reference NSSP Guidance Documents, Chapter II

CONSTITUTION BY-LAWS and PROCEDURES of the INTERSTATE SHELLFISH SANITATION CONFERENCE
PROCEDURE XVI. PROCEDURE FOR ACCEPTANCE AND APPROVAL OF ANALYTICAL METHODS FOR THE NSSP
And:
NATIONAL SHELLFISH SANITATION PROGRAM
Guide for the Control of Molluscan Shellfish 2003

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 At the 2003 ISSC, the Conference accepted the Jellett Rapid Test for PSP as a Type IV screening method with the following conditions:

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

Because the designation as a Type IV Method requires that it be reviewed, the Laboratory Methods Review Committee requested a follow-up report for the 2005 Conference. Procedure XVI, Section 8, Subdivision v. specifies that a Type IV Method is "Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation, adoption by the ISSC, or deletion."

JRT is requesting that the LMR Committee review the data and designate the JRT PSP Test as a Type I or II test for screening with the same restrictions as are currently in place.

Jellett Rapid Testing Ltd. has made test kits available for validation work at half price with the stipulation that the laboratories provide JRT with their validation data. PSP is a phenomenon that occurs seasonally, and some delays were encountered before state programs were able to begin using the kits last year. As a result, some data has been delayed and some will not be available for a few months. JRT prepared and sent a report to LMR Committee members in March and an update will be submitted in June, prior to the ISSC Conference.

Please see attached additional 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; and
(2) The current APHA method used in bioassay for *Karemia breve* toxins.
(3) The Jellett Rapid Test for PSP may be used as a screening method for PSP toxins by regulatory and industry laboratories.

And Recommend modifying the Guidance Document Chapter II Growing Areas Table A. 10. Type I and Type II Marine Biotoxin Methods as follows: Insert Type I or II (as appropriate) under other for Growing Area Survey & Classification, shellfish with the following footnote:

Jellett Rapid Test for PSP
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.
iii. A positive result can be used for a precautionary closure.

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. The Jellett Rapid Test for PSP is not meant to replace the MBA in any way, but rather to augment it by providing an additional layer of food safety that is currently not available.

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 nearshore 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.

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.

The Jellett Rapid Test for PSP could be used to build long term databases on a broader scale than a regulatory lab can afford using only the MBA. These databases could be supplemented with industry testing in areas where there is no testing currently. This would extend, augment and strengthen the current food safety system broadening and refining the food safety net by increasing the number of testing sites and generating long term data in more areas.

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 about $20 (€18). 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 emergency closures, recalls, or providing medical care to those affected by toxic shellfish. In the worst case, it is less expensive than the Mouse Bioassay. Normally, significant economies can be achieved for government and industry through the use of the Jellett Rapid Test for PSP for screening.

Action by 2005 Laboratory Methods Review Committee

Recommended the Jellett Rapid Test for PSP be moved from a Type IV to a Type III method in the NSSP Guidance Documents Table 10.

Action by 2005 Task Force I

Recommended adoption of the Laboratory Methods Review Committee recommendation of Proposal 05-110.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force I.

PSP Validation Data – Interim Report*

California 233 extracts
100% of 2 extracts >80 mcg by MBA[1] were positive by JRT[2]
100% of 20 extracts between 40 and 79 mcg by MBA were positive by JRT
100% of 4 extracts between 32 and 40 mcg by MBA were positive by JRT
(Note that the detection limit of mice is between 32 mcg and 40 mcg depending on the strain of mouse.)
1 invalid test was reported.

New Zealand 154 extracts
100% of 20 extracts >80 mcg by MBA were positive by JRT
100% of 19 extracts between 40 and 79 mcg by MBA were positive by JRT
40% of 5 extracts between 32 and 40 mcg by MBA were positive by JRT
0 invalid tests were reported.

Ireland 69 extracts
0% of 69 extracts were >80 mcg by MBA.
100% of 2 extracts between 40 and 79 mcg by MBA were positive by JRT
9% of 67 extracts with no detectable toxin by MBA were positive by JRT
0 invalid tests were reported.

New York 49 extracts all run with JRT (no MBA analyses were conducted)
All extracts were negative
1 invalid test was reported.

Maine 61 extracts
100% of 14 extracts >80 mcg by MBA were positive by JRT
100% of 21 extracts between 40 and 79 mcg by MBA were positive by JRT
14% of 13 extracts < 46 mcg by MBA were positive by JRT
86% of 13 extracts < 46 mcg by MBA were negative by JRT
0 invalid tests were reported.

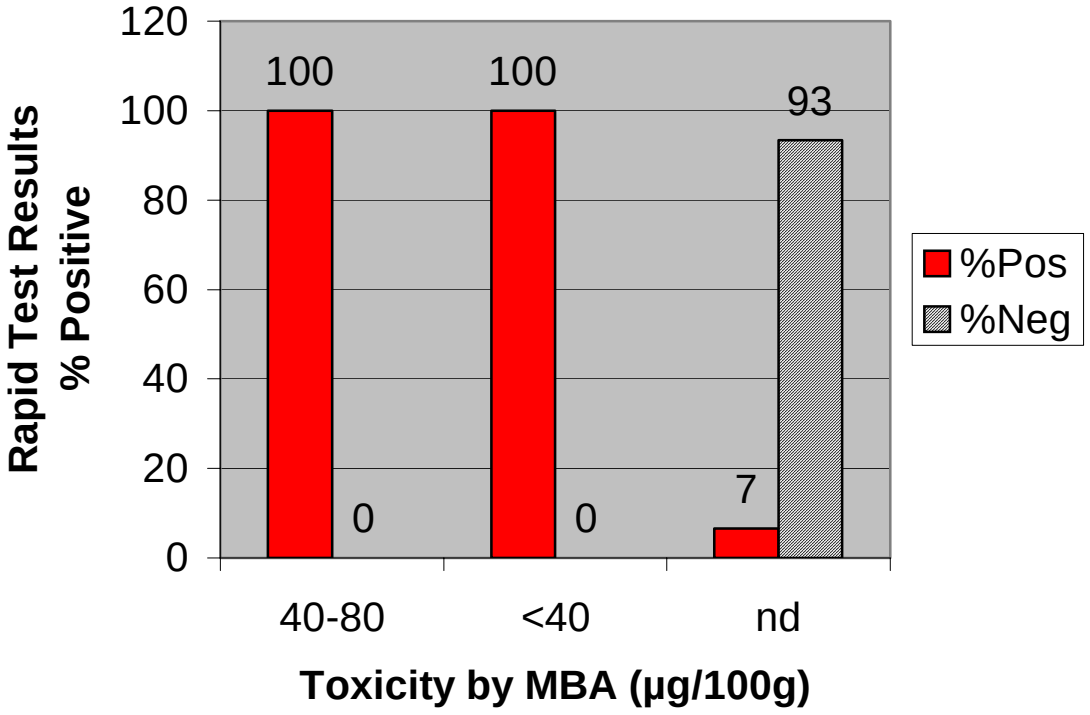
Overall 517 extracts (excludes NY)
100% of 36 extracts >80 mcg by MBA were positive by JRT
100% of 62 extracts between 40 and 79 mcg by MBA were positive by JRT
2 invalid tests were reported.

Because of the variable lower detection limit for the MBA, it is not feasible to summarize the overall data below 40 mcg.

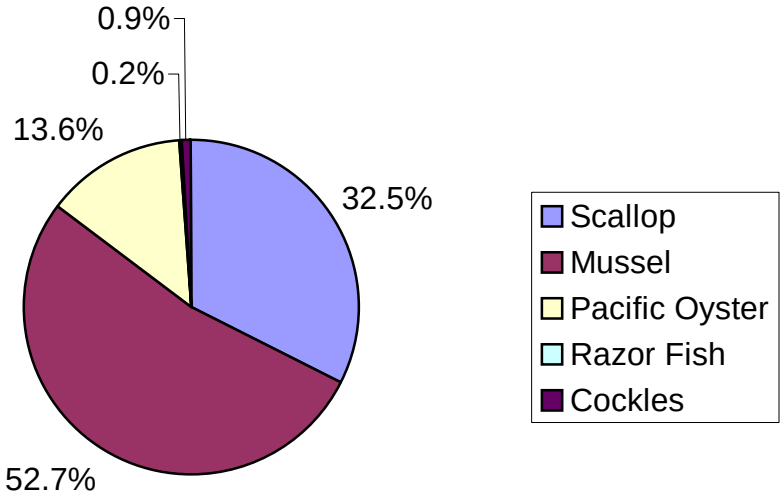
[1] MBA = Mouse Bioassay
[2] JRT= Jellett Rapid Test for PSP

* These data are preliminary and were presented in the report "Summary of Data Submitted to the Laboratory Methods Review Committee Interim Report: January 2005, Issue Number 03-116, Follow-up on Validation Data Jellett Rapid Test for PSP"

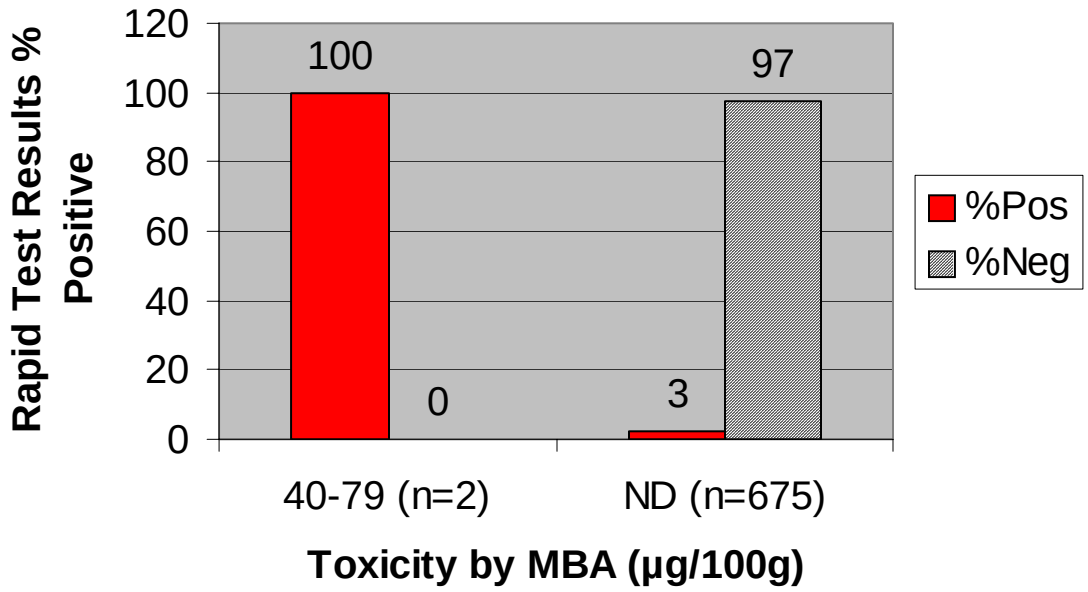
Detection of PSP in Shellfish Tissue from FSAS (UK)
August 2003 to April 2004



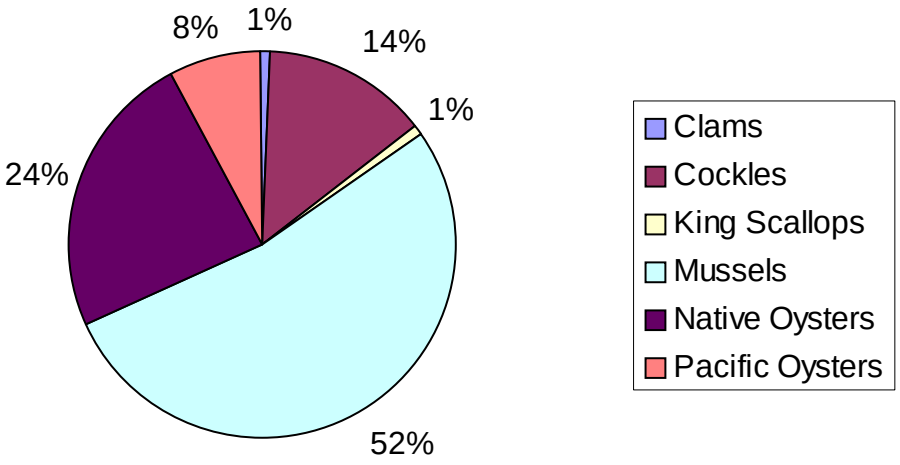
Tissue Types from FSAS (UK) - PSP
August 2003 to April 2004



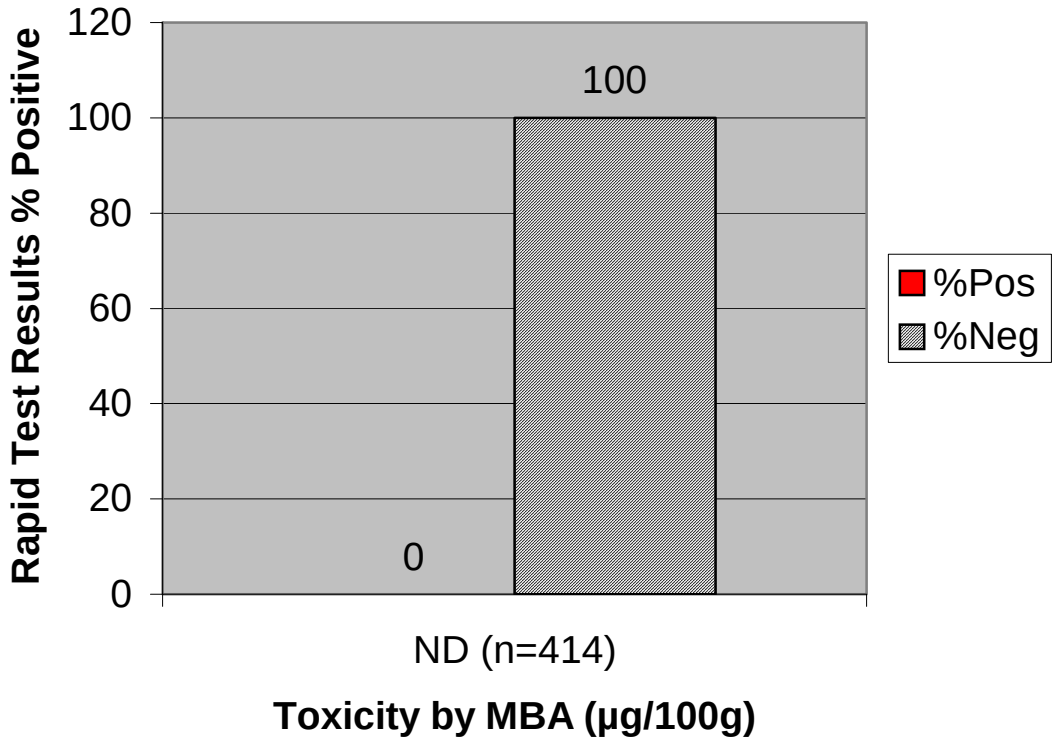
Detection of PSP in Shellfish Tissue From the UK (CEFAS)



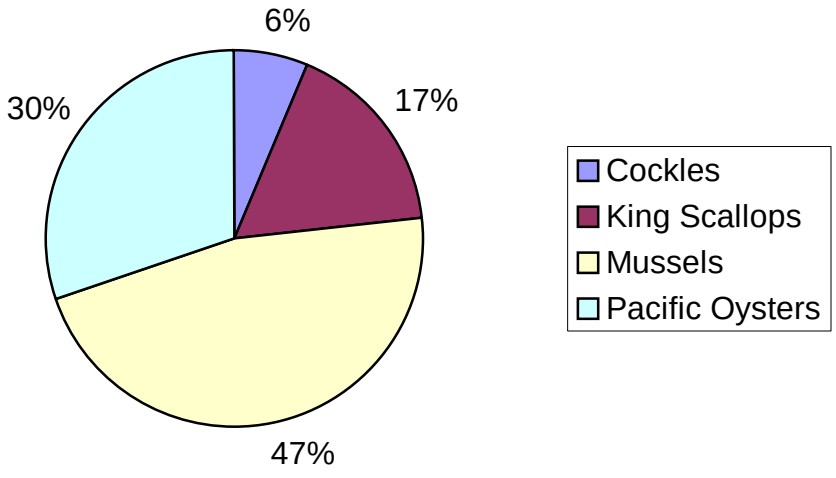
Tissue Types from UK (CEFAS) (n=677)



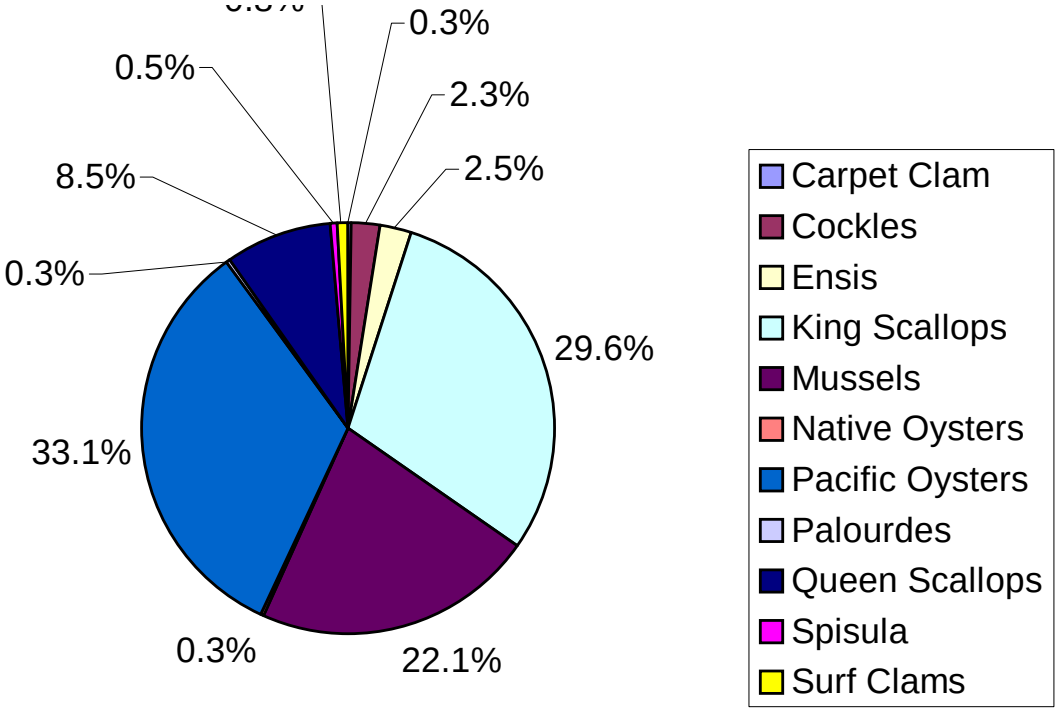
Detection of PSP in Shellfish Tissue from UK (DARD)



Tissue Types from UK (DARD) (n=414)



Detection of PSP in Shellfish Tissue from the UK (FRS)



Tissue Types from UK (FRS) (n=399)