Bureau of Marine Resources - Shellfisheries Section

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Joe Martens
Commissioner

November 15, 2011

Ken Moore, Executive Director
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29233

Re: ISSC Proposal 09-101

Dear Ken,

To establish the context for this letter, and New York's concerns about the adoption of Proposal 09-101 as submitted, I direct you to the actions by 2009 Task Force I which recommended referral of Proposal 09-101 to an appropriate committee as determined by the Conference Chairman and that the Committee should be directed to *gather more information on the standards, **methods and costs***. Those recommendations were accepted by the 2009 General Assembly voting delegates and FDA concurred in February 2010.

Today, I am curious how action by 2011 ISSC General Assembly appears to have adopted an action level for DSP toxins (okadaic acid; OA) in shellfish for which there is apparently no NSSP-accepted lab method by which to determine OA levels in shellfish and for which no costs estimates were provided by the submitter. This recent action seems to ignore the direction adopted by the 2009 General Assembly.

New York's first concern is that this newly adopted action level, 0.16 mg OA equivalents/kg (0.16 ppm), is not expressed in mouse units (MU) and a simple mouse bioassay can't generate results in okadaic acid equivalents/kg (ppm).

New York's second concern is that FDA failed, in both 2009 and 2011, to include any cost information associated with the adoption of the recommended changes. That was either an inexcusable oversight, at best, or a deliberate effort to make it appear that the suggested changes would impose no significant costs upon SSCAs, if the proposal was adopted. Neither reason is a legitimate or acceptable excuse.

New York's third concern is that FDA apparently seeks to compel States' shellfish control authorities to use some test method, other than a relatively simple, fairly inexpensive mouse bioassay procedure, for determining OA levels in shellfish. This is extremely troubling because the 0.16 mg OA equivalent/kg standard seems to necessitate the use of Liquid Chromatography-Mass Spectrometry (LC-MS) or Liquid Chromatography-Functionality Type Distribution (LC-FTD). At least that was reported to us by an FDA staff member familiar with the type of testing necessary to generate OA levels in those units.

New York's fourth concern is that as a result of the adoption of 09-10, as submitted, the ISSC has inexplicably left the SSCAs with no options to test for OA in shellfish, with no test method specified or proposed and, apparently, no emerging testing methods on the horizon.

New York's fifth concern is cost. It has been reported to us that the equipment necessary to perform LC-MS or LC-FTD is complex, sensitive and quite expensive to procure and operate properly.

Another SSCA recently reported that such equipment would likely cost at least **$450,000.** That does not include the personnel cost of employing a staff member with the education and/or training and experience to effectively operate and maintain such equipment.

Our own online search into the cost of such systems determined that the average LC-MS price tag was **$537,000,** with systems ranging from $150,000 to $1.9 million. Even the least inexpensive system is more than three (3) times our current total annual lab budget for supplies and equipment and is, therefore, well beyond our means and not feasible.

Any suggestion that may have been put forth that such LC-MS or LC-FTD equipment probably exists in some other state agency's lab and can be shared by the SSCA is not reasonable. As it was explained to our lab supervisor, that equipment is typically setup to run a specific series or types of analyses and is not readily convertible to the other methods, such as might be required for testing for okadaic acid levels in shellfish tissue extracts. It is easily understandable if another fiscally-stressed state agency would be reluctant to share and re-configure such an expensive, sensitive piece of equipment.

If NYS had a representative at the ISSC meeting, that representative would have insisted that mouse units for DSP be included in what was adopted, at the very least as an interim alternative standard. I believe we would have had support from at least one northeastern state with a robust biotoxin program that has reviewed saxitoxin data generated by a federal lab using LC-MS or LC-FTD and has some questions, based on split samples, about why the federal lab results are not similar to mouse bioassays.

Without being at the ISSC, I cannot know whether these concerns were raised and addressed during review and deliberation of Proposal 09-101. But, I have learned from individuals that did attend the meeting that the conference was primarily focused on *Vibrio* issues, with protracted and intense debate about *Vibrio* proposals, perhaps distracting from the nuances and ramifications of many of the other proposals that were deliberated, particularly lab-related proposals that many consider "too technical."

New York's final and perhaps biggest concern is that that the adoption of DSP standards in 09-101 will either require SSCAs in states facing profound fiscal challenges to make futile attempts to purchase equipment that is extraordinarily expensive to procure, operate and maintain (and, therefore, not possible in NYS at this time) or it will require the SSCAs (in states that can't afford the outlay for LC-MS or LC-FTD equipment and the personnel to operate and maintain that equipment) to pay for outside testing - at who knows what cost, at who knows what outside lab, with who knows what turnaround times for results, using who knows what non-approved method? If fiscally challenged SSCAs cannot afford either of those expensive options, they could be found out of compliance with the NSSP. All because of the lack of including mouse units in the new DSP action level.

Because of the significant costs associated with the adoption of 09-101, as submitted, and the failure of the submitter (FDA) to fully disclose the cost of the implementation of the proposal as submitted, and the potentially profound effects on any SSCA that cannot afford the equipment or the cost of paying for an outside lab to test for OA in shellfish, New York recommends that the changes wrought by the adoption of Proposal 09-101 be deferred until FDA can identify and document those costs (both the

purchase, maintenance and operation (including personnel costs) of the LC-MS or LC-FTD for testing of 100 shellfish samples annually; or, the cost of having 100 shellfish samples tested for OA by some as yet unknown (to NYS and probably most other states' shellfish programs) laboratory that is FDA-approved to generate data that a SSCA can use for decision making purposes. If anyone has the resources to determine those costs it is the U.S. FDA, the original submitter of the proposal.

Alternatively FDA, as the submitter of the proposal, should commit to supporting those states that can neither afford to purchase and operate/maintain the necessary equipment, or pay for testing by an outside laboratory, by agreeing to perform DSP-toxin testing of shellfish samples for those states.

Failing that, the adoption of Proposal 09-101 should be considered invalid because of the obfuscation of the costs of adopting a DSP-toxin action level for shellfish and the apparent lack of an NSSP approved, or proposed, laboratory method for such examinations.

Sincerely,

William Hastback
Acting Shellfisheries Section Head