Proposal Subject	Opening Growing Areas Closed to Biotoxins
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas
Text of Proposal/ Requested Action	@.04 Marine Biotoxin Control C. Closed Status of Growing Areas (4) The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area. A minimum of two (2) consecutive shellfish samples must be collected at least three (3) days apart and the toxin levels must be below the regulatory limit(s) to reopen an area. At the discretion of the Authority, an additional sample may be required before the area is reopened if the toxin levels are just below the regulatory limit.
Public Health Significance	There is growing evidence that toxic algal blooms have been increasing over the last 20 years and not only are becoming more frequent, but more intense, occurring in new places and with longer durations. See, e.g., R.M. Kudela et al. 2015. Harmful Algal Blooms: A Scientific Summary for Policy Makers IOC/UNESCO, Paris (IOC/INF-1320). Because Biotoxins from algae bioaccumulate in shellfish, human and animal consumers of shellfish are at risk from Biotoxin poisoning. Human illnesses caused by consumption of contaminated shellfish include paralytic shellfish poisoning ("PSP"), diarrheic shellfish poisoning and amnesic shellfish poisoning. These illnesses manifest in human victims via symptoms including gastrointestinal disorders and neurologic and muscular problem, including paralysis of the chest and abdominal muscles possibly leading to death (PSP). See Raymond RaLonde (1996), Paralytic Shellfish Poisoning: The Alaska Problem, Alaska's Marine Resources Vol. 8, No. 2. There are no antidotes available to counteract Biotoxin poisoning and victims need immediate medical support. The only reliable means of protecting against the harvest and consumption of Biotoxin-contaminated shellfish is frequent sampling of harvest areas followed by qualified laboratory analysis and quick regulatory action. The presence of Biotoxins in shellfish at harmful or fatal levels cannot be detected by simple observation; affected shellfish do not differ in odor or appearance from shellfish that are safe to consume. Thus in States such as Alaska, where subsistence and recreational harvest of shellfish from unregulated beaches is common; there is a high incidence of PSP illness and even death. Between 1993 and 2014, there were 117 reported cases of PSP poisoning in Alaska, with fatalities occurring in three of those years (1994, 1997 and 2010). Further, because Biotoxin sampling results can vary significantly between lethal and safe levels in just a matter of days, it is unsafe to base a re-opening decision on a single sampling event. For example, geoduck clams sampled in Alaska's Steamboat harvest area on March 9, 2014 returned a paralytic shellfish toxin ("PST") level of 206 ug/100 grams while geoduck sampled from the same area on March 16, 2014 returned a PST level of 57 um/100 grams. With the March 16 sample showing levels below the 80 ug/100 gram closure threshold, Alaska opened the Steamboat area to harvest on March 20, 2014. Just three days later, on March 23, 2014, sampling showed PST levels back to above the closure threshold, at 118 ug/100 grams. The Steamboat area then vacillated between open and closed status weekly until May 10, then remained open until the May 31 PST sample yielded a concentration of 528 ug/100 grams. However, the Steamboat

area reopened on June 7 when the results of one sample were returned at 46 ug/100 grams.

The high volatility of Biotoxin concentrations in shellfish sampled in the same harvest areas can be seen in the attached spreadsheet, which summarizes results of shellfish harvest area PST testing performed by the Alaskan Department of Environmental Conservation ("ADEC") in 2014. Requiring two below-regulatory level Biotoxin tests before re-opening of shellfish harvesting areas will increase confidence that Biotoxin(s) are cleared from the harvest area and that the shellfish are once again safe for human consumption. While this likely will not have a significant impact on growing areas that have fairly consistent PST levels, this will require additional testing in states that reopen areas based on a single test result in growing areas with high degrees of PST variability.

Requiring two below-regulatory limit shellfish samples prior to re-opening an area closed due to Biotoxins will also increase international confidence in the safety of U.S. shellfish, avoiding future potential international bans and sanctions. For example, the proposed PSP testing standards could have avoided certain concerns raised by the Chinese government in 2013.

The Middle Gravina Island growing area in Alaska was implicated in China's 2013 ban of U.S. geoduck. ADEC identifies Middle Gravina Island as an area that consistently exceeds PSP thresholds; in fact, sampling of this area in 2014 showed an average PST level of 312 ug/100 grams. However, commercial geoduck shellfish harvest for human consumption and export occurred in this harvest area in 2013 based on a sub-80 ug/100 gram sample on October 5. The previous week's sample had returned a PST level of 388 ug/100 grams, and the subsequent two samples were 385 ug/100 gram and 528 ug/100 gram, respectively. See ADEC 2013/2014 PSP Lab Results (June 10, 2014). In fact, the only PST sample below regulatory threshold for Middle Gravina Island between September 28 and December 8, 2013 was the October 5 sample.

In summary, increasing the number of tests required before harvest re-opens following a Biotoxin event will reduce public health risks associated with the shellfish industry, boost international confidence in the safety of shellfish products, and minimize the potential that single anomalous readings could authorize the harvest of potentially unhealthy and dangerous shellfish product.

The purpose of the proposal is to set a uniform minimum threshold for State Authority PSP testing. It appears that most State Authorities already meet or exceed the standards proposed herein. In those circumstances, the proposal would not change or alter such regulations.

Cost Information

Although costs will vary by Shellfish Authority, the costs are believed to be minimal. Most ISSC member states and provinces currently use the suggested reopening criteria or one that is already more stringent to manage Biotoxin events. Any costs associated with additional testing would be mitigated by reducing the likelihood of extensive, expensive and time-consuming recalls, international sanctions, and/or the potential repercussions in consumer confidence after illnesses occur.

Action by 2015 Task Force I

Recommended referral of Proposal 15-105 to the appropriate committee as determined by the Conference Chairman.

Action by 2015 General Assembly	Recommended no action on Proposal 15-105. Rationale: The concerns outlined in this proposal are adequately addressed in the NSSP Guide for the Control of Molluscan Shellfish.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15.105 with the following comments and recommendations. Although the ISSC voted no action on Proposal 15-105, discussion of the Proposal raised concerns regarding the adequacy of state Biotoxin sampling strategies. While FDA supports establishment of minimum NSSP sampling requirements for reopening growing areas closed to harvest as a result of unacceptable Biotoxin levels, Proposal 15-105 as submitted was not in keeping with existing NSSP Guidance. Proposal 15-105 proposed reopening an area based on a minimum of two samples collected at least three (3) days apart to demonstrate the return of toxicity levels to below regulatory limits. Existing NSSP Guidance in Section IV. Guidance Documents, Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans recommends, as an example for PSP, collection of three (3) samples over a minimum two (2) week period to demonstrate the return to acceptable toxin levels and to establish a continuing detoxification curve. During discussion of Proposal 15-105, both prior to and during Task Force I, it was apparent that differing opinions and approaches are in play regarding how States manage the reopening of a growing area following a Biotoxin closure. Chapter IV. of the NSSP Model Ordinance requires that closures remain in effect until the Authority has data to show that toxin levels have returned to acceptable levels, but does not include specific sample collection requirements. On the other hand, current NSSP Guidance recommends the development of reopening criteria and outlines the type of criteria that should be integrated, including a sufficient number of samples to establish detoxification curves to levels below regulatory standards and, as stated above, offers a recommended sampling strategy. However, as guidance, those recommendations are not Model Ordinance requirements. To address sampling concerns and needs, the ISSC and FDA should immediately begin discussion regarding establishment of minimum requirements for sample collection and analysis for safely reopening areas following Biotoxin closures. Development of specific reopening criteria is critical to achieving a consistent approach nationally and to enhance the level of safety afforded by the NSSP. Toward that end FDA requests that the ISSC Executive Board further review this issue and take action to consider appropriate NSSP requirements. This effort should include examination of existing practices and the level of safety they provide.