 <p>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</p>	<input type="checkbox"/> Growing Area <input checked="" type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Submitter	Chris Shriver, GM and Daniel Cohen, President
Affiliation	Atlantic Capes Fisheries, Inc.
Address Line 1	16 Broadcommon Road
Address Line 2	
City, State, Zip	Bristol, Rhode Island 02809
Phone	401-253-3030
Fax	401-253-9207
Email	cshriver@atlanticcapes.com and dcohen@atlanticcapes.com
Proposal Subject	Clarification of Surf Clams and Ocean Quahogs Exemption from Time/Temperature Requirements when “intended for thermal processing”.
Specific NSSP Guide Reference	<p>Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls G.</p> <p>Section IV. Guidance Documents Chapter II. Handling, Processing, and Distributing B.</p>
Text of Proposal/ Requested Action	<p>Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls</p> <p>G. Ocean Quahogs (<i>Arctica islandia</i>) and surf clams (<i>Spisula solidissima</i>) are exempt from this temperature control plan when these products are intended for thermal processing, <u>which includes when a Processor represents, labels, or intends for the products to be cooked prior to consumption pursuant to the Processor’s HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations. For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan.</u></p> <p>Section IV. Guidance Documents Chapter III. Handling, Processing and Distributing</p> <p>B. Ocean Quahogs (<i>Arctica islandia</i>) and Surf Clams (<i>Spisula solidissima</i>) are excluded from the time to temperature controls of State Vibrio Control Plans or the matrix outlined in Chapter VIII. @.02 A. (1) (2) and (3). This exclusion applies only when these products are intended for thermal processing, <u>which includes when a Processor represents, labels, or intends for the product to be cooked prior to consumption pursuant to the Processor’s HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations.</u> Authorities may exclude other species when intended for thermal processing. <u>For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan.</u></p>
Public Health Significance	<p>There is no adverse public health significance by this clarification of the meaning of the exemption for surf Clams and Ocean Quahogs “intended for thermal processing”. There will be no change from current practices, which include HACCP process controls adopted by each Processor. The additional wording merely clarifies a misinterpretation that the definition of “intended for thermal processing” is limited to low acid canning of 21 CFR 113.3(o). The Surf Clam and Ocean Quahog processors have been shucking surf clams and selling them in the uncooked state (both as fresh clam meats and frozen clam meats) for decades to customers with the intention that all of their customers will fully cook the Surf Clam meats and Ocean Quahogs prior to consumption. Thermal processing</p>

	<p>and cooked is not limited to only low acid canning, but also includes other forms of cooking and thermal processing as defined in the NSSP MO in Definitions (B) (94). Intended use guidance and controls are already established, this proposal simply clarifies and documents current practices, and aligns with common use of Surf Clams and Ocean Quahogs. As per FDA 21 CFR Part 123 Seafood HACCP regulations the Surf Clam and Ocean Quahog processors shall identify the intended use of their products. Additionally the Surf Clam and Ocean Quahog processors shall be required, consistent with their HACCP Plans, to issue annual HACCP Compliance Letters to all their customers which also identify the intended use of their products.</p>
<p>Cost Information</p>	<p>None. There will be no additional cost to industry, public, or the regulators by this clarification.</p>
<p>Research Needs Information</p>	<p>None. There are no research needs.</p>



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September 11, 2017

Mr. Ken B. Moore, Executive Director
Interstate Shellfish Sanitation Conference
209 Dawson Rd.
Suite 1
Columbia, SC 29223 – 1740

via email: issc@issc.org

RE: Late Submission of ISSC Proposal for Task Force II by Atlantic Capes Fisheries

Dear Mr. Moore,

On behalf of the Atlantic Cape Fisheries, Inc. (“ACF”) I hereby request your approval and the approval of the ISSC Executive Committee for the inclusion and consideration at the Biennial Conference of the ISSC on October 14 – 19 of the attached ISSC Proposal from ACF for consideration by Task Force II.

I understand and appreciate this proposal is being submitted after the June 16 deadline.

Consistent with Article XIII Section 10 please grant an exception and allow consideration of this proposal at the ISSC biennial conference for the following reasons:

- a. Why is proposal being submitted after the deadline? -- The proposal is being submitted after the deadline because the conflict in interpretation of the NSSP Model Ordinance in relation to the time / temperature exemption for Surf Clams and Ocean Quahogs “intended for thermal processing” was not known to ACF prior to the deadline.

- b. Was the information available prior to the deadline? -- ACF only learned of the conflict in interpretation of the wording of “intended for thermal processing” on July 11, 2016 via the submission of a copy of an email from Amy Fitzpatrick, FDA Regional Director, and an Affidavit by Eric Hickey, Deputy Director of the Massachusetts Department of Health (“MA DOH”), in court proceedings between ACF and the MA DOH. The email from Amy Fitzpatrick was not made available to ACF until July 11. Attached please find a letter from ACF to Michael Moore, Director of MA DOH of July 23rd. This letter references the receipt of the email and Affidavit on July 11 wherein the misinterpretation came to ACF’s attention, all after the June 15th deadline.
- c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC? -- As outlined in ACF’s attached letter to Michael Moore of July 23rd, if the interpretation of the time temperature exemption for Surf Clams and Ocean Quahogs applied only when they were low acid canned, it is my contention that every Surf Clam and Ocean Quahog processor has been in violation of this practice for decades. But the practices of the Surf Clam and Ocean Quahog processors to sell their products to other processors, distributors, and consumers with the intention that they will be thermally processed (cooked) has protected the public for decades from outbreaks of illnesses from either Surf Clams or Ocean Quahogs.
- d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change? – Yes, the proposal involves clarifying the meaning and interpretation of the words “intended for thermal processing” in reference to Surf Clams and Ocean Quahogs in the NSSP Model Ordinance. The clarification of the meaning of these four words “intended for thermal processing” will resolve conflicting interpretations by various states and the enforcement of those interpretations for the exemption of time / temperature controls in reference to Surf Clams and Ocean Quahogs when intended for thermal processing. The Surf Clam and Ocean Quahogs industry will be able to continue to operate in the manner it has operated for decades without any history of or threat to public safety after the clarification of meaning of these four words. Additionally state enforcement officials, with greater clarity of the intention and meaning of “intended for thermal processing”, will be able to continue the exemption for the time /temperature controls for Surf Clams and Ocean Quahogs intended for thermal processing consistently throughout all states and throughout the range of the Surf Clam and Ocean Quahog harvests.

As clarified in the proposal, if Surf Clams or Ocean Quahogs are distributed live with the intention they could be eaten in the raw state as defined by the NSSP MO in Definitions (B) (94), those Surf Clams and Ocean Quahogs are not exempt from time / temperature control plans.

ACF has recently met with and reviewed this proposal with other Surf Clam and Ocean Quahogs processors, including but not limited to Sea Watch International, Surfside

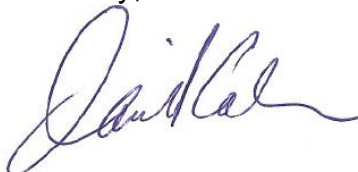
Products, LaMonica Fine Foods, Nantucket Sound Shellfish, and Intershell Seafood. All of these Surf Clam and Ocean Quahog processors agree with the necessity of obtaining this clarification of the wording "*intended for thermal processing*".

Additionally consistent with the attached letter of July 23, 2017 to director Michael Moore, MA DOH, we believe the Commonwealth of Massachusetts and the State of Rhode Island both would benefit from having clarity of the meaning of "*intended for thermal processing*".

Chris Shriver and I will attend the ISSC biennial conference and work with you, your staff, and the other members of the ISSC to assure there is a full hearing and understanding of this request and hopeful its approval during the ISSC biennial meeting.

If you have any questions concerning the above please contact me on my cell phone 609-425-1044.

Thank you for your attention the above,
Sincerely,



Daniel Cohen, President

cc: proposals@issc.org

Chris Shriver, General Manager ACF
Matt Grolnic, QA Director ACF
Michael Moore, Director Massachusetts Department of Health
Eric Hickey, Deputy Director Massachusetts Department of Health
Gary Wolf, FDA
James Meyers, Sea Watch International
Thomas Dameron, Surfside Products
Allen Rencurrel, Nantucket Sound Seafood
Monte Rome, Intershell Seafood
Daniel LaVecchia, LaMonica Fine Foods
David Wallace, Wallace Associates



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July 23, 2017

Michael Moore, Director
Commonwealth of Massachusetts
Department of Public Health
Division of Food & Drugs
305 South Street
Jamaica Plain, MA 02130-3597

Via email: michael.moore@state.ma.us

RE: Modification of Request for Variance Letter

Dear Mr. Moore,

Thank you for the productive discussion of the public health concerns of your office in regards to the surf clam fishery on July 13 with Eric Hickey of your staff and Chris Shriver, Atlantic Capes Fisheries, Inc. ("ACF") General Manager of ACF's Surf Clam Division, Galilean Seafoods, LLC. ("Galilean").

ACF is fully aligned with the goals of your office to assure the Commonwealth of Massachusetts continues to be certified by the FDA as complying with the interstate shellfish regulations of the National Shellfish Sanitation Program and its Model Ordinance ("NSSP MO") as adopted by the US FDA and the Interstate Shellfish Sanitation Conference ("ISSC").

As we discussed, I believe the need for ACF to seek a Variance Letter from the Massachusetts Department of Public Health ("DPH") arises from:

- 1) ACF's previous incomplete education of the DPH of ACF's activities in Massachusetts and therefore a possible misunderstanding by the DPH of the business activities of ACF; and

- 2) From an email from Amy Fitzpatrick of the FDA to the DPH of February 24, 2017 which has raised questions of interpretations of the NSSP MO as it applies to the surf clam and ocean quahog fishery (ACF only learned of this email in court filings of the DPH on July 11).

In the email of February 24, 2017 Ms. Fitzpatrick raises three issues, all of which I address in greater detail below. In summary, though, the issues raised by Amy Fitzpatrick's email reflect the need for clarification of interpretation of the wording of the NSSP MO. Ms. Fitzpatrick correctly indicates that at ACF's Bristol, Rhode Island facility the shucked surf clams are not thermally processed.

But as we discussed the fact that ACF does not "thermally process" all of its surf clam products at its Rhode Island facility does not mean ACF's operations violate the NSSP MO. ACF is FDA and the State of Rhode Island inspected. If the FDA or the State of Rhode Island believed our operations violated the NSSP MO they would require ACF to undertake corrective actions, which we would cooperate to correct. But in fact the FDA and the State of Rhode Island have jointly inspected our Rhode Island operations, including HACCP plan, again in 2017, and never have raised an issue alleging that ACF's surf clam receiving, processing, tagging, and sales violate any of the NSSP MO.

Ms. Fitzpatrick's factual statement that ACF in Rhode Island does not "thermally process" did not address whether ACF's shucked surf clam products are "intended for thermal processing", which is the language of the time temperature control exemptions of the NSSP MO Chapter VIII@.02(G).

The DPH's interpretation of Ms. Fitzpatrick's email, as reflected in Deputy Director Eric Hickey's affidavit of July 11, would make every surf clam processor in Massachusetts also in violation of the NSSP MO, since none of the Massachusetts surf clam processors "thermally process" at their Massachusetts facilities in the manner described in 21 CFR 113.3(o).

RE: NEED TO CONSULT WITH ISSC AND FDA IN REFERENCE TO NSSP MO INTERPRETATION

Under separate cover I intend to send to you a "NSSP MO Strawman Memorandum" wherein I will further outline in greater detail the issues which I highlight below and I believe are not well defined in the NSSP MO in regards to surf clams and ocean quahogs. It is my contention that a narrow view of the NSSP MO would potentially place the majority (likely all) of surf clam and ocean quahog primary processors, not only in Massachusetts but also in other states, in violation of the NSSP MO, without any reported health concerns or illnesses arising from the current practices, which practices have been industry wide for at least 87 years (Soffron Brothers was operating in Ipswich, MA beginning in 1932).

After your receipt of the "NSSP MO Strawman Memorandum" I would appreciate the review and comments by Eric Hickey and your staff. If the MA DPH agrees with my concerns I would hope you could assist me in jointly asking to have those issues outlined in the NSSP MO Strawman Memorandum raised before the ISSC and FDA at the next ISSC Annual Conference in October of 2017, even though the deadline may have technically passed to raise issues for consideration by the ISSC for this annual meeting.

RE: UPDATED VARIANCE REQUEST

The balance of this letter is the formal revised resubmission by ACF to the DPH of ACF's Request for a Variance Letter, which was previously submitted to your office on January 13, 2017 and was formally denied by your office on June 15, 2017. From our discussions last week I learned there were some fundamental misunderstandings of ACF's operations by the DPH which I will clarify hereafter. It is my hope these clarifications will allow DPH to revise its decision and to either determine either:

- a) ACF's operations in Massachusetts are consistent with 105 CMR 500.000 and no Variance is required; or
- b) ACF's operations in Massachusetts require a Variance and therefore the DPH will soon issue a new 2017 Variance Letter to ACF for its operations in Massachusetts.

Clarification #1: Need for a Variance Letter

ACF is of the belief that the only reason a Variance Letter is needed at this time is due to the confusion over interpretation of the NSSP MO. (Hence the collective need for ACF and the DPH to seek clarification and possible changes from the ISSC and FDA at the next annual conference, see above.)

ACF does not believe it is violating any written provision of 105 CMR 500.000. ACF issues with the DPH only arise from the confusion of interpretation of the NSSP MO as called for in 105 CMR 500.021:

"All wholesale dealers and wholesale trucks that handle shellfish shall comply with 105 CMR 500.021.

(A) Requirements for wholesale dealers and wholesale trucks that handle shellfish shall be established as administrative guidelines by the Department, based on the National Shellfish Sanitation Program (NSSP) Model Ordinance (NSSP Model Ordinance), published by the United States Department of Health and Human Services and the Interstate Shellfish Sanitation Conference. All wholesale dealers and wholesale trucks that handle shellfish shall comply with the administrative guidelines."

To the extent the DPH believes this confusion of interpretation calls into question ACF's current practices in Massachusetts and therefore requires a Variance by the DPH, ACF believes the DPH should issue the Variance to ACF as 105 CMR 500.212 states:

"The Department may vary the application of any provision of 105 CMR 500.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice; provided that the decision of the Department shall not conflict with the purpose of 105 CMR 500.000. The Department may place reasonable conditions on any variance."

In that respect, to the extent ACF is continuing industry standard practices (about 87 years) and Galilean specific practices (about 37 years) for the purchase and transport of surf clam shellstock, with no known public health issues arising from those practices, the DPH should be able to find that the shellstock purchasing and transporting protocols of ACF do not conflict with the public health purposes of 105 CMR 500.000. Moreover the DPH should find that stopping ACF from its current transporting protocols as reflected in its FDA approved HACCP plan would be a manifest injustice to the vessel crews, employees, customers, and clam chowder consuming public, with no offsetting public safety benefit.

Clarification #2: ACF is the sum of vertically integrated operational entities and ACF is the “responsible party” for the DPH to look for to comply with DPH policies.

ACF is a vertically integrated shellfish harvesting, processing, and marketing company. ACF and its affiliates (all 100% owned by Daniel Cohen) in its surf clam division, Galilean:

- a) currently own and operate six surf clam harvesting vessels;
- b) purchases surf clams from at least three additionally independently owned surf clam vessels;
- c) which nine vessels are all currently ported and offloaded in Fairhaven, New Bedford, and Hyannis (all nine vessels in Massachusetts);
- d) offloads surf clam shellstock from its state and federally licensed supply vessels at facilities in Massachusetts including public piers (Hyannis), leased facilities (Limberg Marine in Fairhaven), off-loaders providing a service to ACF (Blue Harvest Fisheries, Fairhaven and Sea Watch International, New Bedford);
- e) transports the surfclam shellstock in its own tractor trailers and trucks, which are licensed by the DPH;
- f) and transports the surfclam shellstock in the tractor trailers of Dave Costa, Costa & Sons Trucking (“Costa”) and Rob Gosselin, Gosselin & Son Trucking, Inc. (“Gosselin”) with both Costa and Gosselin being sub-contractors to ACF and should be considered “Employees” of ACF pursuant to definition of Employees in 105 CMR 500.000;
- g) all of whom transport the shellstock from the Massachusetts point of offloading to the ACF shucking facility in Bristol, Rhode Island in less than four hours from port of offloading;
- h) and, despite being less than four hours transit time, ACF voluntarily has adopted in its ACF HACCP plan for the Bristol, Rhode Island plant (and as outlined in our initial Variance Request Letter of January 11, 2016 to the DPH) the NSSP MO protocols for transporting shellstock between Dealers, when the first receiving Dealer receives shellstock above 50 degrees and chooses to ship prior to cooling the shellstock to 45 degrees by the following protocol (in summary):
 - a. The trailer must be pre-chilled to 45 degrees prior to loading the shellstock.
 - b. The trailer must be equipped with a time temperature recording device.
 - c. Upon receipt of the clams at the ACF plant, but prior to their acceptance, inspection of the time temperature recording device must confirm that continuous cooling occurred.
 - d. In the event continuous cooling has not occurred, corrective action as called for in the ACF HACCP plan must be implemented;

- i) after receipt at the ACF shucking facility in Bristol, Rhode Island the shellstock is washed, shucked, sorted, packaged, tagged, and sold by ACF; and
- j) ACF, to facilitate the DPH monitoring of these internally and voluntarily adopted transport controls (which voluntarily hold ACF to standards more stringent than the NSSP MO), has agreed to make all of our receiving and our transport records available to the DPH at our wholly owned scallop processing facility, licensed by the DPH, at 140 Waldron Road, Fall River, MA (IQF Custom Packing, LLC).

In summary, ACF is the responsible party in this entire chain of custody and control of the surf clam shellstock from the point and time of offloading to the production of finished clam meat products for sale to the public.

Clarification #3: Costa and Gosselin are “ACF Employees” and should not be listed on the ISSC

As noted above Costa and Gosselin are ACF Employees per 105 CMR 500.000. It is ACF’s belief that since Costa and Gosselin own tractor trailers they should be licensed by the DPH as a Wholesale Truck. But Costa and Gosselin should not be required to be listed as a Shellfish Shipper on the ISSC. Costa and Gosselin transport activities of shellstock for ACF, as ACF Employees, should be covered by ACF’s listing as a Shellfish Packer (and hence Shipper) on the ISSC.

Clarification #4: Intended for Thermal Processing

It is ACF’s interpretation and the basis of its operations and HACCP plan that all of the surf clam products produced at its Bristol, Rhode Island plant are “intended for thermal processing” by all of its customers, and by the customers of its customers, e.g. also by the consuming public when cooking and preparing at home (even though this represents a small percentage of the market for ACF clam meat products).

As noted above and from the Affidavit of Eric Hickey of July 11, there is a divergence of interpretation of “intended for thermal processing” and what it means for an exception to some of the NSSP MO guidelines. But as also noted above, in relation to ACF’s activities in Rhode Island, this should be not be a concern for DPH, since ACF is not processing in Massachusetts, but only receiving and transporting surf clam shellstock (albeit, out of state).

If ACF’s activities in Rhode Island are violative of the NSSP MO or of the Rhode Island Department of Health’s regulations, it is their responsibility, as guided by the FDA, to seek corrective actions of ACF in Rhode Island, not the responsibility of Massachusetts DPH.

Also, I again note that despite frequent inspections by both Rhode Island Department of Health and the FDA, neither has raised any concern in writing or verbally concerning the fact that in the thermal processing in whole is not being done in our Rhode Island facility. We interpret this lack of concern during multiple inspections by the FDA and Rhode Island inspectors as an endorsement of the ACF clam plant HACCP plan, its controls, and ACF’s consistent marketing of our clam products to customers and consumers who intend to and who do thermally process our clam meats before consumption by consumers.

Moreover if the FDA or Rhode Island took the narrow definition of thermal processing to be only the definition of 21 CFR 113.3(o) by extension the interpretation should apply also to processors in Massachusetts. In this unlikely event, every surf clam processor in Massachusetts would also be in violation (Sea Watch, Intershell, and Nantucket). I am confident this is not the un-intended consequence the DPH was anticipating in its initial denial letter of June 15, 2017.

Clarification #5 – Surf Clam Harvest Vessels Time Temperature control requirements:

As we discussed it is ACF's contention that the "intended for thermal processing" language of Chapter VIII@.02(G) of the NSSP MO exempts surf clam and ocean quahog vessels from the time temperature controls of Chapter [VIII@.02\(A\)\(3\)](#). Therefore ACF has not been monitoring the compliance of its supply vessels to Chapter [VIII@.02\(A\)\(3\)](#).

In the event the DPH believes the surf clam harvest vessels supplying it (and all other Massachusetts Dealers with surf clams intended for thermal processing), the DPH needs to consider that except for a minority of clam vessels with Refrigerated Sea Water ("RSW") systems (only one vessel of the nine surf clam vessels supplying ACF have a RSW system), likely no clam vessel harvesting on Nantucket Shoals (a 10 hour steam) can comply with the current matrix of Chapter [VIII@.02\(A\)\(3\)](#) and land a commercially successful trip. Therefore either:

- a) the matrix of Chapter [VIII@.02\(A\)\(3\)](#) needs to be rethought by the ISSC and FDA at its next annual meeting for the surf clam and ocean quahog fishery; or
- b) the interpretation of Chapter [VIII@.02\(G\)](#) and ACF's understanding of "intended for thermal processing" does exempt the surf clam and ocean quahog fishery from Chapter [VIII@.02\(A\)\(3\)](#); or
- c) Massachusetts, if it seeks to impose time temperature controls on the surf clam and ocean quahog vessels, prior to enforcing needs to educate the vessel operators of these controls, which the vessel operators currently do not believe apply to them. Moreover the Commonwealth of Massachusetts, if it imposes such controls, should consider implementation of a grant or low interest loan program to retrofit vessels for RSW systems, which vessel owners never anticipated capitalizing and which retrofit for many vessels would be an economic hardship.

Clarification #6 – Sushi "live" clams:

As we discussed the surf clams currently harvested and landed in Massachusetts for the Sushi "live" market are not necessarily intended for thermal processing and are therefore are subject to time temperature controls and matrix of Chapter VIII@.02(A)(3).

For clarity ACF currently does not sell or supply this Sushi "live" market, while other surf clam companies in Massachusetts do ship "live clams" for this market.

It is my belief the DPH should consider monitoring the time temperature compliance of this commerce, which is definitively not exempt from the time temperature controls of the NSSP MO.

RE: SUMMARY

In this letter I have attempted to provide rationale why a Variance is not needed by ACF to continue its operations as currently conducted, but if the DPH believes a Variance is needed we have outlined the basis and rationale for the DPH to issue a Variance Letter to ACF.

In the spirit of our meeting of July 13th, I would request that prior to making a decision or issuing a definitive letter in response to this letter that you (or you allow Eric Hickey, your deputy) speak to me on the phone, review any issues contained in this letter which the DPH disputes or takes exception to, and review the terms of a proposed Variance Letter, if the DPH deems it necessary to issue a Variance Letter....so that any unresolved issues can be resolved by additional cooperative communication rather than additional adversarial conflict.

Please contact me with any questions you may have concerning this matter.

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Daniel Cohen".

Daniel Cohen, President - Atlantic Capes Fisheries, Inc.

Cc: Eric Hickey (eric.hickey@state.ma.us)
Chris Shriver, ACF Clam Division General Manager
Matt Grolnic, QA Director – office at IQF in Fall River, MA
Jeff Bolton, COO
Steve Weaver, CFO
Dave Costa
Rob Gosselin
Stephen Ouellette, Esq.

EXHIBIT A

AFFIDAVIT OF ERIC M. HICKEY

I, Eric M. Hickey, do hereby state and affirm as follows:

1. I am the Assistant Director of the Massachusetts Department of Public Health's Food Protection Program.
2. My job duties are to supervise the day to day field operations of the Massachusetts Department of Public Health's Food Protection Program. Additionally I provide interpretation of regulations, program policies and the requirements of the NSSP.
3. I am familiar with 105 CMR 500.000, as well as, the NSSP and work with these documents on a daily basis. I was a member of a committee formed by the Interstate Shellfish Sanitation Conference that developed the time/temperature controls required by harvesters and dealers for transporting and handling molluscan shellfish.
4. The purpose of 105 CMR 500.000 is to establish minimum standards for those persons engaged in the business of preparing, processing, or distributing food for sale in Massachusetts to ensure the public health and safety.
5. In connection with my official duties, I communicate with other state agencies, as well as the FDA regarding food safety. This includes regular discussions relative to the NSSP.
6. The Plaintiff is incorrect when it claims that a consumer cooking the surf clams constitutes "thermal processing." Thermal processing does not refer to an end-user cooking the surf clams, but rather, an application of heat to the surf clams before they arrive to the end-user.
7. According to federal regulations, thermal processing means "the application of heat to food, either before or after sealing in a hermetically sealed container, *for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.*" 21 CFR 113.3(o)(emphasis added).
8. As the consumer cannot be expected to know what period of time and temperature are "scientifically determined to be adequate to ensure destruction of microorganisms of public health significance, it is incumbent upon the Plaintiff to comply with temperature controls.
9. The variance letter states: "[c]ooling the surf clams to 45 [degrees Fahrenheit] . . . is not necessary as they will be intended for thermal processing (shucking)."

10. Shucking is a process whereby surf clams are immersed in heat (i.e., thermal processing) and the shell is then removed.
11. After the variance was issued, I discovered that ACF was not, in fact, utilizing any form of thermal processing, as required by the variance.
12. After the NSSP was revised, I discussed the subject variance with Amy Fitzpatrick of the FDA. Ms. Fitzpatrick stated that the variance did not comply with the revised NSSP. She specifically stated that “[t]he exemption from temperature controls pursuant to 2015 NSSP MO Chapter VIII@02(G.) does not apply because [ACF] is not thermally processing the shellfish.”
13. The DPH is not, has not, and does not “selectively mis-interpret [or] enforce” regulations or the NSSP against ACF or any other entity.
14. All firms operating in Massachusetts are required to comply with 105 CMR 500.000 unless they receive a variance.
15. Only one other firm in Massachusetts had been granted a variance similar to that issued to ACF. However, that firm was notified on February 27, 2017 that it would be required to implement all requirements pursuant to 105 CMR 500.000. Further, that firm had never actually utilized the control parameters of the variance.
16. The DPH is not proposing to prevent ACF from operating in Massachusetts. The variance denial simply requires that ACF operate its business in conformance with the applicable regulations and NSSP. This is required of every firm operating in Massachusetts.
17. In other words, ACF would be able to operate its business so long as it complies with the time to temperature controls outlined in 105 CMR 500.000 and the NSSP. This would require cooling the surf clams to 45 degrees Fahrenheit (or thermal processing the surf clams at its facility). This is required of every firm operating in Massachusetts.
18. The time to temperature controls in the regulations and NSSP are important because they ensure that foods are reasonably safe from pathogens.
19. In this case, the time to temperature controls must be followed, as they prevent microorganisms and foodborne illnesses from permeating the surf clams.

20. The allowance of ACF's Motion would undermine the public health and safety, as food product intended for the public is at risk for development of pathogens. This is especially true of high-hazard foods like shellfish.

SWORN TO UNDER THE PAINS AND PENALTIES OF PERJURY THIS 11TH day of July, 2017.



Eric M. Hickey, Assistant Director
Department of Public Health

EXHIBIT B

Strong, James (DPH)

From: Fitzpatrick, Amy <Amy.Fitzpatrick@fda.hhs.gov>
Sent: Friday, February 24, 2017 3:20 PM
To: Hickey, Eric (DPH)
Cc: Racioppi, John (DPH); Correia, Marc (DPH); Moore, Michael (DPH); Potopsingh, Valerie; Lamoureux, David; O'Malley, Elizabeth; StateRFR-White, Catherine
Subject: RE: Request for Renewal Shellstock Hauling Variance

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Eric,

Based on our conversation last week, and considering the additional details regarding the variance request, namely:

1. I confirmed with the RI DoH that RI 242 SP does not thermally process shellfish.
2. You confirmed that the trucking companies (MA 11439 RS and MA 10728 RS) were re-shippers accepting product from harvesters.
3. You explained that the fishing vessel (F/V) often docks at 0300hrs and half the load is taken onto a truck to ship to RI 242 SP, but half the load remains on the F/V under unknown storage conditions for up to 12-16 hours.

After reviewing the requirements of the 2015 NSSP Model Ordinance (MO)(June 2016), specifically regarding the aforementioned details, I find the following (in the same order as above):

1. The exemption from the temperature controls pursuant to 2015 NSSP MO Chapter VIII @02 (G.) does not apply because RI 242 SP is not thermally processing the shellfish.
2. Pursuant to 2015 NSSP MO Chapter XIV .01, Reshippers shall only reship shellfish obtained from other certified dealers. Reshippers do not buy from harvesters (2015 NSSP MO Section I Purposes & Definitions (101)).
3. Pursuant to 2015 NSSP MO Chapter VIII @.02 (A.)(3.), the storage on the F/V may not meet all of the requirements (depending on average monthly maximum air temperature) for complying with the maximum hours from exposure to receipt at a dealer's facility.

Amy M. Fitzpatrick
Regional Shellfish Specialist

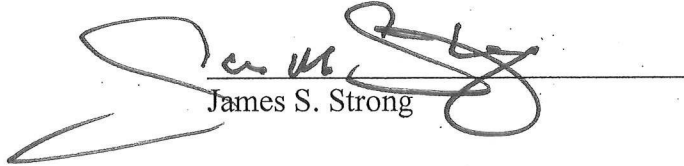
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SENSITIVE/CONFIDENTIAL INFORMATION

CERTIFICATE OF SERVICE

I, James S. Strong, hereby certify that on July 11, 2017, a true copy of the above document was served by in-hand delivery upon all counsel of record.


James S. Strong