Proposal No. 2 7 - 2 6 1

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	1) Joe Kalmin (Director, Policy & Government Affairs); 2) Keith Jackson (Vice President, Corporate Quality Assurance)
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9. Proposal Subject	Lack of Time Temperature Consideration and Ambient Air Temperature Monitoring During Conveyance Consideration for Controlling *Vibrio* Pathogen Growth and Toxin Formation for Shellstock Reshippers.
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIV. Reshipping .01 Critical Control Points.
11. Text of Proposal/ Requested Action	IFDA formally requests that the NSSP Model Ordinance expressly include the option for Shellstock Reshippers (Chapter XIV) to monitor for proper mechanical refrigeration through transit at the Receiving Critical Control Point, as this would be aligned with the guidance published throughout the rest of the Model Ordinance, as well as aligned with the FDA guidance outlined in the *Fish and Fishery Products Hazards and Control Guidance-June 2022 Edition* for controlling pathogen growth. ***Chapter XIV. Reshipping*** *.01 Critical Control Points* *A. Receiving Critical Control Point - Critical Limits.* *(1) The dealer shall reship only shellfish obtained and transported from a dealer who has:* *(a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the inshell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and* ***[C]*** *(b) Provided documentation as required in Chapter IX. .05; and* ***[C]*** *(c) Adequately iced the shellstock; or* ***[C]*** *(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; or* ***[C]*** *(e) Shipped the shucked, in-shell, ~~shellfish~~ and/or live molluscan shellstock ~~in-shell product adequately iced or~~ in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature, which has not been permitted to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C).* ***[C]*** *... C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:* *(1) Iced; or* ***[C]*** *(2) Placed and stored in a storage area or conveyance maintained at 45 °F (7.2 °C) or less; and~~-~~* ***[C]*** *(3) Permitted to remain without ice, mechanical refrigeration, or other*

	approved means of storage for no more than two (2) hours at points of processing or transfer such as loading docks. ***[C]*** D. *Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45 °F (7.2 °C) or less or covered with ice; and not be permitted to remain without ice, mechanical refrigeration, or other approved means of storage for more than two (2) hours at points of processing or transfer such as loading docks.* ***[C]***
12. Public Health Significance	The proposed revisions would not have a negative impact on public health. Industry has historically measured the ambient air temperature of the conveyance to monitor receiving CCPs, and there is no indication that this practice poses risks to public health or consumer safety. In fact, data from Sensitech provided with this submission show, with proper placement of the time/temperature recording device on the outside of the case, the representative internal temperature of the product is comparable to the ambient air temperature. In contrast, requiring internal product temperature readings for each lot may create potential food safety risks by eliminating visibility into shipping temperatures and would result in significant operational challenges and additional costs for industry resulting from regulatory action without achieving a measurable benefit in public health. Indeed, monitoring conveyance temperature is better protective of public health as it demonstrates continual temperature control throughout transportation and provides a holistic view of the cold chain of the product, rather than a one-time product temperature check. Finally, shellstock dealers (specifically shellstock shippers and reshippers) have previously been permitted to use documentation and records that reflect that shellstock was transported from the previous certified dealer in a conveyance at or below 45 °F (7.2°C) without harming public health. We note that this approach is consistent with FDA's approach to sanitary transportation for other food systems.[1] Further, FDA's guidance, *Fish and Fishery Products Hazards and Control Guidance* (2022) provides a relevant example of a critical limit for fish products delivered refrigerated. This example requires that "lots received are accompanied by transportation records that show that the product was held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit."[2] This example suggests ambient air temperature reading at receipt is an appropriate way to monitor the CCP. Additionally, the *Fish and Fisheries Hazard Control Guidance* (Appendix 4; pg. 421, Table A-2), outlines the established maximum cumulative time and temperature safe exposure combinations for fish and fishery products with respect to pathogens of greatest concerns.[3] This data can be extrapolated for shellfish/shellstock and, as shown in the table below, the proposed limits of (1) a maximum of two hours without mechanical refrigeration and (2) ambient temperatures not to exceed 70°F (21.1 °C) are in line with the data on the growth of *Vibrio parahaemolyticus* and *Vibrio vulnificus*.

[1] See, Sanitary Transportation of Human and Animal Food, 81 Fed. Reg. 20092 (Apr. 6, 2016).
[2] Fish and Fishery Products Hazards and Controls Guidance: June 2022 Edition, page 220, FDA (June 2022) available at: https://www.fda.gov/media/80637/download.
[3] Fish and Fishery Products Hazards and Controls Guidance: June 2022 Edition, page 418, 421, FDA (June 2022) available at: https://www.fda.gov/media/80390/download.

	GROWTH OF ***VIBRIO PARAHAEMOLYTICUS*** — 41-50°F (5-10°C): 21 days; 51-70°F (11-21°C): 6 hours; 71-80°F (22-27°C): 2 hours; Above 80°F (27°C): 1 hour[2] GROWTH OF ***VIBRIO VULNIFICUS*** — 46.4-50°F (8-10°C): 21 days; 51-70°F (11-21°C): 6 hours; 71-80°F (22-27°C): 2 hours; Above 80°F (27°C): 1 hour[2]
13. Cost Information	No cost to industry would be incurred with the proposed changes. Failure to consider the proposed changes will lead to product rejections of shellstock, shucked, and in-shell products considered time-temperature abused based on current 2023 Model Ordinance language.
14. Changes Needed to Guidance (if proposed change is adopted)	**Section IV, Chapter XIV, Page 432:** "Should the shipping dealer have chosen to ship product harvested under the time temperature requirements of Chapter VIII. @.02 A. (3) or restricted use shellstock prior to achieving required internal temperatures, the shellstock must be accompanied by a time/temperature recording device which indicates that continuing cooling has occurred. The shipment must also be accompanied by a shipping document indicating the time of shipment and that all shipping containers were prechilled. Shellfish and ~~S~~sshellstock acceptability (receiving Critical Control Points) can be determined as follows: 1. The presence of enough ice to contact the shellfish and provide cooling to achieve required internal temperatures; or 2. An ambient temperature of 45 °F (7.2 °C) or less in the conveyance as measured by a thermometer or a time/temperature recording device demonstrating the shellfish and shellstock was not permitted to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C); or…" **Section IV, Chapter XIV, Page 433:** "Prying open the shells of shellfish is a time consuming and inherently destructive process (those animals measured must be discarded). The internal temperature of shellstock is, under most circumstances, reflected by the external temperature of the space surrounding the shellfish, or the external temperature of the shell of the animal, at the center of a packaged mass of shellstock (box, sack, bag, etc.). This temperature may be measured by (1) inserting a standard analog or digital thermometer probe into the package to an appropriate depth; ~~or~~ (2) ~~by~~ exposing the shellfish at the center of the package for rapid measurement of the external shell temperature such as is made possible with laser guided infrared temperature measurement devices~~.~~ ; or (3) recording the ambient air temperature in conveyance through the use of a time/temperature recording device demonstrating the shellfish and/or shellstock was not be permitted to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C)." **Section IV, Chapter XIV, Page 434:** "Should the shipping dealer have chosen to ship product harvested under the time temperature requirements of Chapter VIII. @.02 A. (3) or restricted use shellstock prior to achieving required internal temperatures, the shellstock must be accompanied by a time/temperature recording device which indicates that continuing cooling has occurred. The shipment must also be accompanied by a shipping document indicating the time of shipment and that all shipping containers were prechilled. Shellfish and ~~S~~sshellstock acceptability (receiving Critical Control Points) can be determined as follows: 1. The presence of enough ice to contact the shellfish and provide cooling to achieve required internal temperatures; or 2. An ambient temperature of 45 °F (7.2 °C) or less in the conveyance as measured by a thermometer or a time/temperature recording device demonstrating the shellfish and shellstock was not permitted to remain without mechanical refrigeration at or above 45 °F (7.2 °C) ambient air temperature for more than two (2) hours, never to exceed 70 °F (21.1 °C); or…"