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)
3. Affiliation	1) International Foodservice Distributors Association, as representative of Performance Food Group, Sysco, and others; 2) Performance Food Group
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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 Shippers.
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping .01 Critical Control Points
11. Text of Proposal/ Requested Action	IFDA formally requests that the NSSP Model Ordinance expressly include the option for Shellstock Shippers (Chapter XIII) 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 XIII. Shellstock Shipping*** *.01 Critical Control Points* *A. Receiving Critical Control – Critical Limits.* *... (2) The dealer shall ship or repack only shellstock obtained and transported from a dealer who has:* *(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05; 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, and/or live molluscan shellstock in a conveyance at or below 45 °F (7.2 °C) ambient air temperature and has not permitted the shucked, in-shell, and/or live molluscan shellstock 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]*** *... (4) The dealer shall ship or repack only in-shell product obtained from a dealer who has:* *(a) Shipped the in-shell product* *(i) Adequately iced; or* *(ii) In a conveyance at or below 45 °F (7.2 °C) ambient air temperature and has not permitted the in-shell product 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 ***[C]*** *(iii) At an internal temperature of 45 °F (7.2 °C) or less; and* ***[C]*** *(b) Identified the in-shell product with a tag on each container.* ***[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 not stored in a storage area or conveyance without ice, mechanical refrigeration, or other approved methods of storage, as required in Section .01 B. (1) or Section .01 B. (2) (a) or (b) for more than two (2) hours at points of processing or transfer.* ***[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

[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.

<table>
<tr><td></td><td>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.

<table>
<tr><td>GROWTH OF VIBRIO PARAHAEMOLYTICUS</td><td>41-50°F (5-10°C)
51-70°F (11-21°C)
71-80°F (22-27°C)
Above 80°F (27°C)</td><td>21 days
6 hours
2 hours
1 hour[2]</td></tr>
<tr><td>GROWTH OF VIBRIO VULNIFICUS</td><td>46.4-50°F (8-10°C)
51-70°F (11-21°C)
71-80°F (22-27°C)
Above 80°F (27°C)</td><td>21 days
6 hours
2 hours
1 hour[2]</td></tr>
</table>
</td></tr>
<tr><td>13. Cost Information</td><td>No cost to industry or regulatory bodies 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.</td></tr>
<tr><td>14. Changes Needed to Guidance (if proposed change is adopted)</td><td><u>Section IV, Chapter XIII, Page 430:</u>
“Dealers receiving shellfish and/or shellstock from another certified dealer for shipping and repacking must document and maintain a record that the shellfish and/or shellstock was received iced; in a conveyance at or below 45 °F (7.2 °C) ambient air temperature and was not 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 at an internal temperature of 50 °F (10 °C) or less. Dealers receiving shellfish and/or shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellfish and/or shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.”

<u>Section IV, Chapter XIII, Page 431:</u>
“Shellfish and ~~S~~shellstock acceptability (receiving Critical Control Points) can be determined as follows:
1. The presence of enough ice on the shellfish to 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; or…”</td></tr>
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