Proposal No. **23-204**

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Proposal Subject	Proposal for Clarifying Wet Storage Holding Temperatures for Shipped Shellstock
Specific NSSP Guide Reference	Chapter XIII. Shellstock Shipping .01 Critical Control Points (A) (2)(d) and (B)(2)(b)
Text of Proposal/ Requested Action	Under the current language in the Model Ordinance, shellstock shipped to another approved dealer, must be held under 45F. Per Chapter XIII. .01 B. (2) (b); "…be placed in a storage area or conveyance maintained at 45 F or less. Additionally, per Chapter XIII. .01 A (2) (d) "Shipped the shellstock in a conveyance at or below 45 F ambient air temperature; and (e) Cooled the shellstock to an internal temperature of 50F". It seems the primary concern in holding pre-chilled shellstock is an internal temperature of less than 50F. However, these rules are written under the language of Cold Storage, or chilled conveyances, this language does not consider validated artificial wet storage systems. To maintain an internal temperature of less than 50 F in Cold Storage, the temperature of the cold storage system must be set to less than 45 as the difference between the chiller and the internal temperature will vary by a few degrees. In an artificial wet storage system, the temperature of the chiller and the internal temperature of the animal will vary by ~1 degree. So, in theory you are not permanently raising the holding temperature of pre-chilled shellstock by putting them in wet storage of 50 F or less. Local authority has been clear to our company that holding temperatures of shipped shellstock must be held at 45 F or less, as to match the temperature of the conveyance it was shipped on. We are requesting guidance documents or language changes to Chapter XIII. .01 B that would allow pre chilled shipped shellstock to be held in a validated Wet Storage system at 50 F or less.
Public Health Significance	Maintaining the internal temperature of shipped shellstock within a wet storage system.
Cost Information	No cost to authorities, potentially significant cost savings to shippers with energy savings.
Action by Task Force II, 2023	Recommends adopting proposal 23-204 with amended language: Chapter XI. Shucking and Packing B. Shellstock Storage Critical Control Point – Critical Limits. The dealer shall ensure

	that: (1) If wet storage or depuration ~~in artificial bodies of water~~ is practiced, water quality meets the requirements outlined in Chapter VII for wet storage for chapter XV for depuration..~~04; and~~ [C] (2) Once placed under temperature control and until shucked the shellstock shall; : (a) Be placed in wet storage or depuration; or [C] (~~a~~b) Be iced; or [C] (~~b~~c) Be placed and stored in a storage area or conveyance maintained at 45 F (7.2 C) or less; and [C] (~~c~~d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer, such as loading docks. [C] ~~Not be permitted to remain without ice, mechanical refrigeration or other approved methods of storage, as required in Section .01 B. (1) B. (2) (a) or (b) for more than two (2) hours of points of processing or transfer such as loading docks. [C].~~ Chapter XIII. Shellstock Shipping B. Shellstock Storage Critical Control Point – Critical Limits. The dealer shall ensure that: (1) If wet storage or depuration ~~in artificial bodies of water~~ is practiced, water quality meets the requirements outlined in Chapter VII for wet storage for chapter XV for depuration..~~04; and~~ [C] (2) Once placed under temperature control and until shucked the shellstock shall; : (a) Be placed in wet storage or depuration; or [C] (~~a~~b) Be iced; or [C] (~~b~~c) Be placed and stored in a storage area or conveyance maintained at 45 F (7.2 C) or less; and [C] (~~c~~d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer, such as loading docks. [C] ~~Not be permitted to remain without ice, mechanical refrigeration or other approved methods of storage, as required in Section .01 B. (1) B. (2) (a) or (b) for more than two (2) hours of points of processing or transfer such as loading docks. [C].~~
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-204
Action by FDA July 7, 2023	The FDA does not concur with Conference action to adopt proposal 23-204 as amended by Task Force II. The initial proposal requested guidance on maintaining wet storage water temperatures at ≤50°F instead of ≤45°F since the NSSP allows internal temp of shellstock to be ≤50°F. The rationale provided was that wet storage water temps are more representative of internal temps than in dry storage. Task Force II discussed the request for guidance, drafted edits to language in Chapters

XI and XIII, and recommended adoption by the General Assembly. The language that was recommended and subsequently adopted by the General Assembly is as follows where it occurs in Chapter XI .01 B. (2) and Chapter XIII .01

B. (2):

"B. (2) Once placed under temperature control and until shucked the shellstock shall:

a) Be placed in wet storage or depuration; or [C]
b) Be iced; or [C]
c) Be placed or stored in a storage area or conveyance maintained at 45°F (7.2°C) or less; and [C]
d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than 2 hours at points of processing or transfer, such as loading docks. [C]"

It is FDA's position that the adopted language is in direct conflict with the principles of 21 CFR 123, *Seafood HACCP Regulation* and the policy outlined in the Fish and Fishery Products Hazards and Controls Guidance, 4th edition (2022 version) (Hazards Guide). CFR 123 and NSSP Guide Chapter X. .01 A. stipulate dealers conduct a hazard analysis which identifies critical control points (CCP) in their process where they can control identified species and process related hazards. Original dealers are responsible for demonstrating the control of pathogen growth from the growing area via critical limits (CL) that demonstrate the hazard has been controlled. At the Receiving CCP, dealers show controls from the harvest area via approved source labeling (tags, harvest controls) and the documentation of time of harvest to time in temperature control during Vibrio control months. The harvest/process related hazard of pathogen growth is controlled at the Storage CCP via the CL of temperature (≤50°F prior to shipping, with a <10-hour clock attached during Vibrio control months).

Since the original dealer is responsible for demonstrating control of the hazard, secondary dealers need only demonstrate how they are maintaining control of the hazard through temperature control until it reaches the final destination (point of sale - where food code takes over). Those controls are demonstrated via documentation of adequate ice/internal temperature of shellstock/temperature of cooler and that shellstock shall not remain out of that temperature control for more than 2 hours at points of processing or transfer.

In other words, once the hazard has been controlled by the original dealer, everyone down the chain documents how it stays in control through their Receiving CCP (receiving temperature), and Storage CCP (temperature of cooler/ presence of ice) showing it can keep that hazard controlled. The reason for having "not to remain out of temp control for more than 2 hrs" is to maintain the control established by the original dealer. All tags/labels are required to say "KEEP REFRIGERATED" for the same reason.

Temperature is our only barrier to control pathogen growth in shellstock (outside of post-harvest processing). Once the original dealer has demonstrated product has been cooled to ≤50°F and controlled the hazard, secondary dealers taking it out of temp control for wet storage or depuration goes against the established principles of CFR

	123 and basically re-introduces the hazard. Please see Chapter 12 of the Hazards Guide for Control Strategy 2- Refrigerated Storage and Refrigerated Processing Control as well as Control Strategy 4- Unrefrigerated Processing Control, and Table 12-5 which shows no more than 2 hours >50°F to ensure control of pathogen growth for ready to eat product. The original dealer controls the potential hazards from the growing area (Chapter 2) and then they and everyone else who touches the product maintains the control via temperature ≤50°F (Chapter 12). In summary, the adopted language allows for potential re-introduction of a hazard that original dealers have controlled if temperature control is not maintained down the chain of custody. FDA recommends that Proposal 23-204 be sent to Committee for further discussion.
Action by ISSC executive Board October 19, 2023	FDA was in nonconcurrence with the action taken by the conference because it is FDA's position that the adopted language is in direct conflict with the principles of 21 CFR 123, Seafood HACCP Regulation and the policy outlined in the Fish and Fishery Products Hazards and Controls Guidance, 4th edition (2022 version) (Hazards Guide). This action will not be published due to being in conflict with federal regulation and Proposal 23-204 will be reconsidered at the next conference.