Proposal No. 2 7 - 2 5 0

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	U.S. Food & Drug Administration (FDA)
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9. Proposal Subject	Receiving critical limit for federal waters
10. Specific NSSP Guide Reference	NSSP Model Ordinance, Section II, Chapter X. General Requirements for Dealer, Chapter XI. Shucking and Packing, .01 Critical Control Points, A. (1) and Chapter XIII. Shellstock Shipping, .01 Critical Control Points, A. (1)
11. Text of Proposal/ Requested Action	Chapter X. .06 Shucked Shellfish Labeling A. Shellfish Labeling. (1) The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers. (2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing: (a) The original shucker-packer's name and certification number; (b) The shucking date; and (c) The quantity of shellfish per container and the total number of containers. (d) All restricted shucked shellfish shall include a label containing all information required in Section .06 of Model Ordinance Chapter X. In addition, the label will include specific language detailing the restrictions requiring further processing or testing prior to distribution. Chapter XI. .01 Critical Control Points A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; or[C] (b) Harvested restricted shellstock and properly tagged with information describing the restriction; [C] (c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C] (d) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

	(e) Harvested the shellstock from federal waters in compliance with a NOAA SIP contract, and if applicable, a state issued license, and are listed on the NOAA SIP Contract Harvester List. [**C**] B. – E. F. Receiving restricted shellfish shucked from shellstock harvested from federal waters is labeled in compliance with X. .06 and not released for sale or shipment prior to testing results required under the NOAA SIP contract. [C] Chapter XIII A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall ship or repack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]** (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and **[C]** (c) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) **[C]**. (d) Harvested the shellstock from federal waters in compliance with a NOAA SIP contract, and if applicable, a state issued license, and are listed on the NOAA SIP Contract Harvester List. [**C**]
12. Public Health Significance	Dealers receiving shellstock from harvesters that harvest in federal waters must have a critical limit in their HACCP plan at the receiving critical control point. Dealers must obtain shellstock from federal waters from harvesters with a NOAA contract and if applicable, a state issued license. Currently, there is no requirement for restricted shucked shellfish labeling in Chapter X. .06. For example, shellfish that has been shucked and shipped for further processing that was harvested in areas designated in the controlled access status in federal waters. There is only a requirement in Chapter X. .05 for shellstock with restricted tags. There are known instances of federal waters restricted shucked shellfish being shipped that have not met all conditions of harvest restrictions prior to being placed in distribution per Chapter IV. @.04 B. (2)(h) Dealers receiving shucked shellfish from shellstock harvested in federal waters must have a critical limit in their HACCP plan. If receiving federal waters shucked shellfish prior to testing and release for distribution must hold product until testing and release under the NOAA SIP contract as having met all conditions of release.
13. Cost Information	Minimal cost for implementing an additional critical limit.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD