Proposal No. **17-223**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Address Line 1	5001 Campus Drive
Address Line 2	CPK1, HFS-325
City, State, Zip	College Park, MD 20740
Phone	240-402-1401
Fax	301-436-2601
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	*V.p.* Levels During Wet Storage
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping .01 Critical Control Points
Text of Proposal/ Requested Action	B. Shellstock Storage Critical Control Point – Critical Limits. The dealer shall ensure that: (3) All oysters and/or hard clams harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements: (a) Cooled to an internal temperature of 55° F (12.7° C) within the time periods outlined in the State V.v. Control Plans. [C] (b) Cooled to an internal temperature of 50° F (10° C) within the time periods outlined in the State V.p. Control Plans. Shellstock cooled to an internal temperature of 55° F (12.7° C) to comply with a V.v. Control Plan is considered in compliance with this requirement. [C] (4) When held in land based wet storage or depuration, the dealer must demonstrate, through a validation study, the process does not increase levels of Vibrio. The validation study must be approved by the State Shellfish Control Authority with concurrence from the FDA. The dealer must have a verification procedure approved by the State Shellfish Control Authority. [C] (5~~4~~) All other shellstock obtained from a licensed harvester shall be placed in a conveyance pre-chilled or a storage area maintained to 45° F (7.2° C) or less and cooled to an internal temperature of 50° F (10° C) prior to shipment. [C] (6~~5~~) Product intended for relay~~, wet storage or depuration,~~or either geoduck clams (*Panopea generose*), or Mercenaria sp. which are being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed above in .01 B. (4) above. [C]
Public Health Significance	When *Vibrio* spp. are present in the waters used for wet storage and depuration, or present in the oysters and/or hard clams placed there, there is the potential for a significant hazard if the conditions become favorable for vibrio growth. An informal investigation into a partial list of illnesses reported through the FDA Regional Shellfish Specialists from 2011 – 2016 reveal approximately 20 *V.p.* illnesses associated with wet stored or depurated product. During the associated traceback investigations, no deficiencies were noted regarding compliance with harvester time to temperature requirements under Vibrio Control Plans.

	In addition, data are not available to confirm that the contact time of UV to water in a re-circulating wet storage/depuration UV system is sufficient to significantly reduce vibrios present in the water. Rapid changes in environment (temperature, salinity, etc.), such as transfer to wet storage or depuration, can cause shellfish to cease, or reduce, pumping which can allow the growth of vibrios inside the shellfish. Data, such as, confirming the effectiveness of UV treatment on vibrios in depuration water, as well as demonstration of active pumping of shellfish, could be provided to ensure the holding of shellstock in a wet storage or depuration system is not increasing the risk from vibrio.
Cost Information	