Proposal No. 1 7 - 2 0 4

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
Submitter	US Food & Drug Administration (FDA)
Affiliation	FDA
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Add in-field Compliance Criteria for Control of Harvest Element
Specific NSSP Guide Reference	Section II. Model Ordinance - Chapter I@03B.3
Text of Proposal/ Requested Action	1. ~~Patrol~~ Control of Harvest (Change "Patrol Element" to "Control of Harvest Element" in Chapter I@03B.3 Section.) a. Requirements for evaluation …. (new) i. In-field (Harvester) Compliance Criteria i. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. **95% of harvesters have valid license Critical** ii. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education. **A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing. At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. The harvester shall maintain record of the completed training.** **100% of licensed harvesters have required training within specified time.Critical** iii. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall: Be a dealer; or Pack shellstock for a dealer. **95% of harvesters engaging in shellfish packing meet this requirementCritical** iv. Non-Vessel Harvesting. Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination,

deterioration, and decomposition.

95% of the non-vessel harvesters meet this requirement Key

v. Vessels. The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.

95% of the harvest vessels meet this requirement Key

Cats, dogs, and other animals shall not be allowed on vessels.

95% of the harvest vessels meet this requirement Key

Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

100% of harvest vessels meet this requirement

Critical

As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

95% of the harvest vessels meet this requirement Critical

~~i.~~**vi. Shellstock Washing. The harvester shall be primarily responsible for washing shellstock.**

If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility. Water used for shellstock washing shall be obtained from: A potable water source; or a growing area in the: Approved classification; or in the open status of the conditionally approved classification.

If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI. 02 A. (3) and Chapter XIII. 02 A. (3).

95% of the harvesters meet this requirement

Critical

v. Shellstock Identification. Each harvester shall affix a tag that meets Chapter

	VIII.02.F to each container of shellstock which shall be in place while the shellstock is being transported to a dealer. **95% of the harvesters meet this requirement** **Critical** vi. Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities meets the requirements of Chapter VIII02.F(7). **95% of the harvesters utilizing bulk tagging meet this requirementCritical** **Shellstock Temperature Control. All harvesters shall comply with the applicable time to temperature requirements of a State *V.v.* and *V.p.* Control Plans outlined in Chapter II. @.06 and @.07; or Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3). All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements.** **95% of the harvesters meet these requirements** **Critical** **ji. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above ~~patrol~~ Control of Harvest evaluation criteria.** i. The overall ~~Patrol Program~~ Control of Harvest element will be assigned one of the following designations: (a) **Conformance:** The program is in compliance with all of the criteria listed above. (b) **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item. (c) **Non-Conformance:** The program has: i. at least one (1) critical deficiency; ii. ~~two (2)~~ four (4) or more key deficiencies; or iii. a repeat **[Key]** deficiency from the previous evaluation. (d) **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.
Public Health Significance	Adds in-field compliance criteria to address Control of Harvest Element evaluation activities related to NSSP MO Chapter VIII Requirements for Harvesters. Proposal will bring in the in-field compliance criteria which is similar to plant compliance criteria which have administrative and in-field components.
Cost Information	N/A

Action by 2017 Task Force II	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chair with instructions that this proposal be assigned to the appropriate multiple committees.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-204.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-204.
Action by 2019 NSSP Evaluation Criteria	Recommends the Conference Chairperson establish a workgroup including members from the NSSP Evaluation Criteria Committee and the Patrol Committee to review and make recommendations to the conference on proposal 17-204 working with FDA to consider consistency and uniformity of evaluation criteria for all program elements.
Action by 2019 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-204.
Action by 2023 Control of Harvest Evaluation Criteria	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Control of Harvest Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-204.