Proposal No. 2 7 - 2 3 1

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	US Food and Drug Administration (FDA)
3. Affiliation	US Food and Drug Administration (FDA)
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9. Proposal Subject	Aquaculture Operational Plan Implementation
10. Specific NSSP Guide Reference	Section II Model Ordinance - Chapter VI. Shellfish Aquaculture .03 B., .04 A., .05 A. and .07 B.
11. Text of Proposal/ Requested Action	Requested action: Add the phrase 'and implement' to Chapter VI. Shellfish Aquaculture sections .03 B., .04 A., .05 A. and .07 B. Chapter VI. Shellfish Aquaculture .03 Seed Production in Water Classified as Prohibited or Unclassified Seed may come from any growing area, or from any growing area in any classification, providing that: A. … B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have and implement a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) … (2) … (3) … (4) … (5) … (6) … .04 Aquaculture that Attracts Birds or Mammals A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have and implement a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) … (2) … (3) … (4) … (5) … (6) … (7) … .05 Land Based Aquaculture A. Operational Plan. Each facility shall have and implement a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:

	(1) … (2) … (3) … (4) … (5) … (6) … (7) … (8) … (9) … (10)… B. … C. … D. … .07 Requirements for the Harvester in Aquaculture in Federal Waters A. … B. Operational Plan. Each aquaculture facility shall have and implement a written operational plan as described for Land Based Aquaculture in Section II Chapter VI. .05 (A).
12. Public Health Significance	The Model Ordinance requires operational plans for each aquaculture site that cultures seed in prohibited or unclassified waters, if the Authority determines the aquaculture site may attract birds and/or mammals in sufficient numbers to present a human health risk, for land base aquaculture facilities and for aquaculture in federal waters. The Model Ordinance further requires that the Authority approve the operational plans prior to implementation. However, there is no requirement in the Model Ordinance for the aquaculture operator to actually implement the operational plan. Aquaculture operational plans should be specific to the firm and the activities they are conducting. In some cases, the aquaculture facility has a generic operational plan that is not specific to the firm's operations. Since the plan is not specific to the firm's operation, the plan cannot be effectively implemented. The plan may contain requirements that the firm is not meeting. For example, an operational plan may require bird deterrent measures, but the firm is not employing them. In this example, the firm has a plan, but has not implemented the controls or requirements specified in the plan. By adding the phrase 'and implement' to the current MO language, the firms would be required to not only have a plan, but to put the requirements and controls in the plan into practice. Adding the phrase also gives the Authority regulatory language to point to if firms fail to have controls specified in their plan in place. For comparison, a similar requirement is specified in the Model Ordinance with respect to having and implementing a written HACCP plan (Chapter X. .01 B). Adding the phrase 'and implement' to the requirement to have a written operational plan will add consistency to the requirements of the Model Ordinance.
13. Cost Information	There would be no cost to the industry or Authority related to this proposal.

14. Changes Needed to Guidance (if proposed change is adopted)	TBD