

Questions and Answers from September 17, 2020 FDA/ISSC Informational Meeting.

The Q&A and Chat were downloaded and organized from the meeting. I tried to organize and blend based on topic in the event someone who didn't attend would like to follow along, however, there may be some questions in the wrong order under the topic. When it says "answered" it was addressed by the speaker.

AQUACULTURE CHAPTER OVERVIEW

1. Bob R: since "market size" is not defined in the MO - how do you propose to use that term?
Kris Phelps: answered
2. Dani Toepelt: Do flip bags that are directly on the beach (not suspended) need to be evaluated as well?
Kris Phelps: state will need to determine.
3. Adam Wood: Do you have a reference section in the NSSP that regulates hatcheries? especially for maintenance of 2 years of record retention.
Kris Phelps: Hi Adam: Hatcheries are exempt
4. Vanessa Zubkousky-White: Do we need to issue permits for all aquaculture facilities? Or only the 3 types of high risk (birds, seed, land)?
Kris Phelps: answered
5. Vanessa Zubkousky-White: It seems that the NSSP states that all aquaculture facilities need a permit, not just for high risk. How is this interpreted? "Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain: (1)A permit from the Authority for the activity and functioning of his facility;"
Kris Phelps: answered
6. Michael Bott: does remote setting if it is in prohibited water count if it's used for bottom planting?
Kris Phelps: answered
7. Michael Bott: then would they need to have annual inspection? what about if state beds are supplemented by remote set spat on shell?
Kris Phelps: answered- needs follow up
8. Michael Bott: thank you and i heard half of it
David Wiggins: Mike this is a state run example of using set as a resource enhancement or an Aquaculture facility doing this
9. Adam Wood: What states have had to close aquaculture operations due to increased bacteria? How big are those operations?
10. Adam Wood: where are the bylaws for the ISSC located?
Kris Phelps: www.issc.org
Adam Wood: path...
Kris Phelps: Conference Administration...Constitution, Bylaws, and Procedures

11. Bill D: USDA APHIS hosts an aquaculture sector meeting every year. As an outcome of this year's virtual meeting in June. APHIS committed to hosting a webinar for shellfish farmers who need assistance with bird management and harassment techniques in order to comply with the new ISSC requirements related to bird waste. I understand a planning committee met in July.

EU UPDATE ANNOUNCEMENT

12. Raymond Burditt: ShellfishEquivalence@fda.hhs.gov
Kris Phelps: thank you Raymond- here is the email again
13. Kathy Brohawn: May want to consider a different format for future meetings, this one keeps bombing out either audio or presentations and I have to reload over and over
Kris Phelps: Thanks, Kathy- noted!

CHAPTER II RISK ASSESSMENT AND RISK MANAGEMENT CHANGES

14. Adam Wood: What is the level of genetic typing that will be acceptable...will the expectation be that just going to the genotype level will be acceptable?
Kris Phelps: answered
15. Adam Wood: I mean genogroup.
Kris Phelps: clarifying word to previous comment
16. Kathy Brohawn: Are written procedures required in the MO
Kris Phelps: discussing...
Kathy Brohawn: when there is no illness are written procedures required?
Kris Phelps: Chapter I @.01F is written protocol with epidemiologists
Kathy Brohawn: Lizzy is not answering my question
Lizzie: Hi Kathy,
If you want to talk about it let me know. I am not sure what specifically you are asking. If you are asking if you are required to have an SOP for illnesses, that answer is no. But if you are asking if there are things you must have written, then yes there are and I went through what they are, so when you look at the presentation you will see where those items are. Just to recap, you can find the requirement in Ch 1 @01 F for how you work with your epis or other agencies in investigations, (remember the discussion of 17-205), if there is an illness there must be a summary, and if there is a contingency or management plan obviously that must be written. Does that help? There will be other things that you will write obviously, but regarding requirements in the MO for what we need to have written, that is what we have. :)
17. Alex Manderson: Epis can be in other states that I may be working with. I won't have agreements with Epis in Georgia or North Carolina.
Kris Phelps: Answered

MARINE BIOTOXIN CONTROL: 2019 MO CHANGES

18. Heather Merritt: Why were requirements listed in the guidance document instead of listing them in the model ordinance section?
Kris Phelps: answered
19. Heather Merritt: I think "guidance" implies that the content is voluntary. Maybe there should be a different section called addendum for details.
Kris Phelps: answered

Heather Merritt: thank you

20. Todd Egerton (Virginia): Are there specific approved methods required for shellfish testing option? Can commercial ELISA test kits be used for this routine purpose (not for reopening)?
Kris Phelps: answered
21. Adam Wood: Are all of these numbers and strategies linked to Control plans and not Contingency Plans?
Kris Phelps: answered
22. Adam Wood: Thank you
23. Kathy Brohawn: Stacey, is this in guidance for management strategies
Kris Phelps: answered
24. Kathy Brohawn: I mean the monitoring frequency
Kris Phelps: clarifying question
Kathy Brohawn: is monitoring frequency relating to management plan not contingency
Kathy Brohawn: ok, got it
Kathy Brohawn: thank you
25. Alex Manderson: So we have maintained a robust shellfish toxicity program over a number of decades. However, this monitoring occurs on the coastline and not specifically within a commercial growing area. Would the coastline that connects with the estuarine growing area be considered a hydrographically linked water body?
Kris Phelps: answered
26. Alex Manderson: yes thank you
Lizzie: no. I don't believe we do
27. Kristina Broussard: Do these triggers need to be established per Genus/Species?
Kris Phelps: answered
28. Kristina Broussard: You just answered my question. Thanks!
29. Patricia Rabideau: Will Stacey's presentation be available by email?
Kris Phelps: answered
30. Tom Dameron / Surfside Foods: How do Federal Waters move to the opened and closed status?
Kris Phelps: answered
31. K Stryker: This was presented as a proposal that simply documented what states were already doing and was not intended to change a state's current program. As a result, I supported the proposal and recommended passing it. It sounds like that isn't the case. Can you help me understand?
Kris Phelps: answered
32. John Miller: PSP approved testing method other than the Mouse Bioassay process
Kris Phelps: answered

33. Kristina Broussard: Is there guidance on all of the species that need thresholds?
Kris Phelps: answered
34. Kathy Brohawn: comment: Would love to see the Eliza method approved for okadaic acid have we gotten further in this
Kris Phelps: answered
35. Katherine Groff: Will this include ISSC's effort to provide definitions for groups of shellfish (i.e., when a method is approved for clams – what types does that include?)
Kris Phelps: answered

MISCELLANEOUS

36. Tori Stivers: For future meetings, it would be helpful if hosts could give general guidance on how to use Adobe Connects before presentations start. Could show those instructions on screen starting 15 minutes before meeting start.