

**PROCEEDINGS OF THE  
ATLANTIC STATES MARINE FISHERIES COMMISSION  
HORSESHOE CRAB MANAGEMENT BOARD**

**Beaufort Hotel  
Beaufort, North Carolina  
Hybrid Meeting**

**October 16, 2024**

**Approved April 30, 2024**

**TABLE OF CONTENTS**

Call to Order, Chair John Clark ..... 1

Approval of Agenda ..... 1

Approval of Proceedings from May 3, 2023..... 1

Public Comment ..... 1

Set 2024 Delaware Bay Harvest Specifications ..... 1

    Review Horseshoe Crab and Red Knot Abundance Estimates and Model Results from the Adaptive Resource Management Framework Revision ..... 2

    Set 2024 Specifications ..... 4

Consider Results of Stakeholder Survey on Delaware Bay Management Objectives ..... 5

Consider Approval of FMP Plan Review and State Compliance for 2022 Fishing Year ..... 11

Report on Status of Synthetic Endotoxin Testing Reagents ..... 13

Review and Populate Advisory Panel Membership ..... 15

Other Business..... 16

    Response to Earth Justice/Shoemaker Horseshoe Crab ARM Framework Analysis..... 16

Adjournment ..... 18

## INDEX OF MOTIONS

1. **Approval of Agenda** by consent (Page 1).
2. **Approval of Proceedings of May 3, 2023** by consent (Page 1).
3. **Move to accept the 2024 Adaptive Resource Management harvest specifications with 500,000 males and no female harvest on Delaware Bay-origin crabs. In addition, the 2:1 offset will be added to MD's and VA's allocations due to no female harvest** (Page 5). Motion by Shanna Madsen; second by Craig Pugh. Motion passes by unanimous consent (Page 5).
4. **Move to use the Stakeholder Survey Report as a basis for a Horseshoe Crab Management Objectives workshop, which would include a small group of managers, scientists, and stakeholders to explore different management objectives for the Delaware Bay-origin horseshoe crabs. This workshop should focus on multi-year specification setting and modeling approaches when selecting no female harvest. The intent would be to provide a report to the full Board in time for the 2025 specification setting process** (Page 11). Motion by Shanna Madsen; second by Joe Cimino. Motion passes by unanimous consent (Page 11).
5. **Move to approve the FMP Review, state compliance reports, and de minimis requests for South Carolina, Georgia, and Florida for the 2022 fishing year** (Page 12). Motion by Mike Luisi; second by Emerson Hasbrouck. Motion passes by unanimous consent (Page 12).
6. **Move to approve Advisory Panel nomination for Sam Martin from Maryland** (Page 16). Motion by Mike Luisi; second by Shanna Madsen. Motion passes by unanimous consent (Page 16).
7. **Move to task the Adaptive Resource Management Subcommittee with preparing a response to the September 2023 review of the ARM Framework by Dr. Kevin Shoemaker** (Page 16). Motion by Bill Hyatt; second by Mike Luisi. Motion passes by unanimous consent (Page 18).
8. **Move to adjourn** by consent (Page 18).

## ATTENDANCE

### Board Members

Dan McKiernan, MA (AA)	Mike Luisi, MD, proxy for L. Fegley (AA Acting)
Raymond Kane, MA (GA)	Russell Dize, MD (GA)
Sarah Ferrara, MA, proxy for Rep. Peake (LA)	Shanna Madsen, VA, proxy for J. Green (AA)
Conor McManus, RI, proxy for J. McNamee (AA)	Chris Batsavage, NC, proxy for K. Rawls (AA)
David Borden, RI (GA)	Jerry Mannen, NC (GA)
Justin Davis, CT (AA)	Chad Thomas, NC, proxy for Rep. Wray (LA)
Bill Hyatt, CT (GA)	Mel Bell, SC (AA)
Jesse Hornstein, NY, proxy for M. Gary (AA)	Malcolm Rhodes, SC (GA)
Emerson Hasbrouck, NY (GA)	Ben Dyar, SC, proxy for Sen. Cromer (LA)
Joe Cimino, NJ (AA)	Spud Woodward, GA (GA)
Jeff Kaelin, NJ (GA)	Erika Burgess, FL, proxy for J. McCawley (AA)
John Clark, DE (AA)	Ingrid Braun, PRFC
Roy Miller, DE (GA)	Chris Wright, NMFS
Craig Pugh, DE, proxy for Rep. Carson (LA)	Rick Jacobson, US FWS

**(AA = Administrative Appointee; GA = Governor Appointee; LA = Legislative Appointee)**

### Ex-Officio Members

Brett Hoffmeister, Advisory Panel Chair	Nicholas Couch, Law Enforcement Representative
John Sweka, ARM Subcommittee Chair	

### Staff

Bob Beal	Kristen Anstead	Tracey Bauer
Toni Kerns	Katie Drew	James Boyle
Tina Berger	Jeff Kipp	Caitlin Stark
Madeline Musante	Jainita Patel	Chelsea Tuohy

### Guests

Max Appelman, NOAA	Jeff Brunson, SC DNR	Scott Curatolo-Wagemann,
Mike Armstrong, MA DMF	Jeffrey Brust, NJ DEP	Cornell Cooperative Extension
Pat Augustine	Allen Burgenson, Lonza	of Suffolk County
Jason Avila	Debbie Campbell	Bill DeSteph, Senate of VA
Richard Balouskus, RE DEM	Averi Chen	Phil Edward, RE DEM
Linda Barry, NJ DEP	Haley Clinton	Julie Evans, Evans
Meredith Bartron, US FWS	Allison Colden, CBF	Communications
Alan Bianchi, NC DMF	Heather Corbett, NJ DEP	Emily Farr, Manomet
Nora Blair, Charles River Labs	Margaret Conroy, DE DNREC	Lynn Fegley, MD (AA)
Emily Bodell, NEFMC	Egan Cornachione, Senate EPW	F Joel Fodrie, Institute of
Jason Boucher, NOAA	Committee	Marine Sciences (UNC-CH)
William Brantley, NC DMF	Jamie Cournane, NEFMC	Marty Gary, NY (AA)
Robert T. Brown	Caitlin Craig, NYS DEC	Pat Geer, VMRC

**Guests (continued)**

Shirley Goffigon, Fujifilm Wako  
Chemicals USA Corp.  
Joe Gresko, CT (LA)  
Joseph Grist, VMRC  
Will Harlan, Center for  
Biological Diversity  
Allie Hayser, Manomet  
Karen Hedstrom  
Derrek Hughes, NYS DEC  
Jon Hurdle, NJ Spotlight  
Richard Jacobson, US FWS  
Gregg Kenney, NYS DEC  
Blaik Keppler, SC DNR  
Jennifer Lander, NYS DEC  
Christina Lecker, Fujifilm Wako  
Chemicals USA Corp.  
Ben Levitan, Earthjustice  
Susan Linder, Horseshoe Crab  
Recovery Coalition  
Chip Lynch, NOAA  
Tobias Mattes, Associates of  
Cape Cod  
Nichola Meserve, MA DMF  
Steve Meyers

Tina Moore, NC DMF  
Trevor Moss  
Allison Murphy, NOAA  
Josh Newhard, US FWS  
Thomas Newman  
Conor ODonnell, NH FGD  
Ronald Owens, PRFC  
Bridget Pegg  
Derek Perry, MA DMF  
Michael Pierdinock  
Will Poston  
Tracy Pugh, MA DMF  
Paul Rago  
Kathy Rawls, NC (AA)  
Zoe Read, WHY  
Allen Reneau, Fujifilm Wako  
Chemicals USA Corp.  
Paul Risi  
Katherine Rodrigue, RI DEM  
Mike Ruccio, NOAA  
Brendan Runde, TNC  
Christopher Scott, NYS DEC  
Claire Shanklin, Senate EPW  
Committee

Alexei Sharov, MD DNR  
Ethan Simpson, VMRC  
Fletcher Smith, GA DNR  
Bryan Sparrow, Fuji Film Wako  
Chemicals USA Crop.  
Renee St. Amand, CT DEEP  
Benjie Swan  
Rachel Sysak, NYS DEC  
Yoshihiro Takasuga  
Mike Thalhauser, ME Center for  
Coastal Fisheries  
Laura Tomlinson, MA DMF  
Troy Tuckey, VIMS  
Beth Versak, MD DNR  
Mike Waine, American  
Sportfishing Assn.  
Maureen Ward, Horseshoe  
Crab Conservation Assn.  
Craig Weedon, MD DNR  
Kristoffer Whitney  
Daniel Zapf, NC DEQ  
Jordan Zimmerman, DE DFW  
Erik Zlokovitz, MD DNR

The Horseshoe Crab Management Board of the Atlantic States Marine Fisheries Commission convened in the Rachel Carson Ballroom via hybrid meeting, in-person and webinar; Monday, October 16, 2023, and was called to order at 3:15 p.m. by Chair John Clark.

### **CALL TO ORDER**

CHAIR JOHN CLARK: Welcome to the Horseshoe Crab Board. I think most of the Board is here and getting to the table. We are running behind, so I will talk fast. Welcome everybody. I am the Chair for the meeting, I'm John Clark from Delaware. I'm joined up here by Program Plan Coordinator extraordinaire, Caitlin Starks.

We have from the Law Enforcement Committee, Captain Nick Couch from Delaware, and we also have our Assessment Wonder Team here of John Swika and Kristen Anstead here, so we are well represented up front.

### **APPROVAL OF AGENDA**

CHAIR CLARK: Let's move right into the Consent Agenda. The agenda, right now there will be a change in the agenda you have.

The Item Number 5 will be considered before Item Number 4, so Item 5 becomes Number 4. In addition, we will have an Other Business Item, actually I think there is a couple of Other Business items that will come up, so we will get to that at the Other Business section of the agenda. Are there any other revisions to the agenda? Seeing none; the agenda is approved by consent.

### **APPROVAL OF PROCEEDINGS**

CHAIR CLARK: Are there any changes or revisions to the proceedings from the May, 2022 meeting of this Board? Seeing none; the proceedings are approved by consent.

### **PUBLIC COMMENT**

CHAIR CLARK: Do we have any public comment? Okay, this is public comment for items that are not on the agenda. Is there anybody in the room that

has any comment? Not seeing any hands, we do not have comments.

### **SET 2024 DELAWARE BAY HARVEST SPECIFICATIONS**

CHAIR CLARK: Now we'll move right into Agenda Item 4, which is Item 5 on your agenda. Take it away, John.

DR. JOHN SWEKA: As you all remember, the ARM Framework was revised and accepted for management use back in 2022. Under Addendum VIII, the ARM Framework will be used annually to produce state harvest recommendations to the Delaware Bay. Within that Addendum we have a maximum harvest that can be recommended of either 210,000 females and 500,000 males. Last year 125,000 females and 475,000 males were recommended for the 2023 harvest season.

However, the Board did elect to implement a 0 female harvest last year. Within the ARM Framework, the overall objective statement, as you've all seen before, is to manage harvest of horseshoe crabs in the Delaware Bay to maximize harvest, but also to maintain ecosystem integrity, provide adequate stopover habitat for migrating shorebirds, and ensure that the abundance of horseshoe crabs is not limiting the red knot stopover population or slowing recovery. The data that go into the ARM on an annual basis that we use then to make a decision, includes the red knot population estimates from a mark-resight analysis. This is conducted by Jim Lyons of USGS, and is based on visual counts of birds along Delaware Bay beaches, along with the number of birds that showed unique flags or marks on their legs.

The horseshoe crab population estimates come from three trawl surveys, the Virginia Tech Trawl Survey, the Delaware Adult Trawl, and the New Jersey Ocean Trawl Surveys. These trawl surveys then are incorporated into what is known as our Catch Multiple Survey Analysis Model, which also includes bait landings, dead discards and biomedical mortality, to ultimately come up with a population estimate of horseshoe crabs.

**REVIEW HORSESHOE CRAB AND RED KNOT  
ABUNDANCE ESTIMATES AND MODEL RESULTS  
FROM THE ADAPTIVE RESOURCE MANAGEMENT  
FRAMEWORK REVISION**

DR. SWEKA: Here we have the red knot population estimates through time, dating back to 2011. These are the mark-resight population estimates that as I mentioned, Jim Lyons calculates these each year for us. In 2023, there were 39,361 red knots with confidence intervals ranging from 33,000 to 47,000. In 2022 there were 39,800 red knots, with confidence intervals ranging from 35,000 to 51,000.

When we make an annual harvest recommendation, for this year we will actually use the 2022 estimate, and this aligns the bird count, along with the population estimate of horseshoe crabs from 2022, which is the time period for which we have complete data for. Don't worry, there is two-year delay between when we have our population estimates from 2022, when harvest would be implemented in 2024.

That two-year time lag was incorporated in the ARM optimization. For female harvest of horseshoe crabs, this is a time series going back to 2003. You can see in more recent years the female harvest in the bait landings has declined greatly, because of the annual ARM recommendation of 0 female harvest.

The black portion of these bars are the dead discards, and in 2016 to 2021, the dead discards went up for females quite a bit, and that was because we had a very high dredge ratio, which influences the overall estimates. Now we must admit that our estimates of dead discards are pretty uncertain. There is a lot of variability, and just reporting issues within the NEFOP data to generate those.

The gray bars here represent biomedical mortality, and in the interest of protecting confidential data, here we represent the biomedical mortality as the total coastwide biomedical mortality, assuming it all comes from Delaware Bay. This graph just shows the male harvest through time. You can see since

2013 the bait landings are obviously much higher than that for males than they are for females, because we have consistently recommended 500,000 bait harvest.

But in reality, even the bait harvest, even though the ARM had recommended 500,000, still are a few hundred thousand less than the actual ARM implementation through time. Again, in black there are the dead discards, and in gray the coastwide biomedical mortality. Moving on to the indices of abundance. These are the female indices of abundance of horseshoe crab from the various trawl surveys. The first line I want to draw your attention to is the black solid line. That represents the fully mature or the multiparous animals from the Virginia Tech Trawl Survey. You can see in the last two years we've hit our greatest number over the course of the time series. The black dash line represents the newly mature, or the primiparous crabs in the Virginia Tech Trawl Survey.

Over the last couple years, it's been very low, and in fact it was 0 in 2022. I'll discuss this more as we move on in the presentation. The other trawl surveys there, the gray dash line represents New Jersey Trawl Survey, and it had some missing years due to COVID pandemic, but came back online in 2022.

The most recent values through New Jersey Trawl Survey happens to be the highest value over the time series, dating back to 2003. Then finally, the solid gray line is Delaware Trawl Survey, and since approximately 2010, 2011, it has shown a consistent increase through time. Likewise, the male horseshoe crab indices, again Virginia Tech in black there.

The two highest values occurred in the last two years for the multiparous for mature individuals. The newly mature or primiparous individuals, they were more than what the females were. You can see in 2022 was actually the highest value for newly mature individuals from the Virginia Tech Trawl Survey.

Then likewise, the Delaware and New Jersey Trawl

Surveys, they generally showed an increase since about 2010. I mentioned the Virginia Tech had 0 primiparous, or newly mature individuals in 2022. Well, this is a problem. This is a problem for our catch multiple survey analysis, and we had to come up with a way to address it.

In 2022, 0 primiparous or newly mature individuals. The catch multiple survey analysis is really a simple state-structured model that sums the newly mature plus the mature animals. Subtract the harvest and natural mortality, and then predict the population next year. If you have a 0 in there, the model will not run.

This is concerning, and we've discussed it among the Technical Committees, three possible hypotheses for why the Virginia Tech Trawl Survey ended up with a 0 year. One of them could be catchability. Perhaps the catchability between the fully mature and newly mature individuals has changed, or suddenly changed through time, and the trawl survey just don't encounter them.

Second hypothesis is a recruitment failure. Perhaps approximately ten years ago something caused a decline in the new female horseshoe crabs that has then become evident here in recent years, or the third thing is possibly an identification issue within the Virginia Tech Trawl Survey. Perhaps many of the newly mature individuals are being misidentified as fully mature individuals.

Of these three possible hypotheses, it seems to me that the recruitment failure one is probably the least likely, because it is difficult to think of some sort of a mechanism, where newly mature males continue to increase, where females all of a sudden tanked and dropped off to 0. You know what would it be that would affect immature female crabs and not immature male crabs. This is an issue that the Technical Committees have given quite a bit of thought to and discussion. One way that we could deal with this, we had to come up with a method to fill in this gap from 2022, with a 0. We looked back at the time series of data from 2003 to 2019. The newly mature portion of the female population is approximately 20 percent of the total mature, you

know the newly plus the mature.

That was very consistent up until 2019, and then all of a sudden, the newly mature animals just seemed to kind of disappear. We also have some corroborating evidence from the Delaware Trawl Survey, which in recent years also started to stage crab. From 2017 to 2022, Delaware comes up with nearly the same proportion of newly mature individuals at 19.86 percent. Both lines of evidence show that typically there is about 20 percent newly matured animals in the mature population.

The ARM and the Delaware Bay Ecosystem TC decided to adjust the 2020 to 2022 data, so that the newly mature females are approximately 20 percent of the total mature population. This maintained a total number of mature crabs, but this also allows us then to continue to run the catch multiple survey analysis.

This is also supported by the biology of the horseshoe crab. It doesn't seem like we could possibly get the increase in mature females, without some level of newly mature females also being in the population. It doesn't make sense that they would increase, but you didn't have any newly mature entering the population.

This graph just shows the Delaware adult trawl survey partitioned into mature and newly mature individuals. You can see how the two track each other through time. Here we have just a percent newly mature in the Virginia Tech Trawl Survey and also the Delaware Trawl Survey. As you can see from 2003 up through 2018, on average we're right about 20 percent in the Virginia Tech Survey.

But then all of a sudden in 2019 it declines greatly. Whereas, in the Delaware Trawl Survey we're still on average around 20 percent there. When we take all this information and put it into the catch survey analysis model, this is the population estimate for mature females in the Delaware Bay through time, starting in 2003 up through 2022.

You can see our point estimate at this point in time is the highest it has been yet. In the Catch Multiple



Survey Analysis, we conducted two ways to show publicly. We consider coastwide biomedical mortality, and then absolutely no biomedical mortality, and kind of bracket where the truth is. You can see that the inclusion or exclusion of biomedical mortality makes very, very little difference, and in fact these lines are basically on top of one another.

Here we have the population estimates coming out of the catch multiple survey analysis model for males. Then again, the point estimate is at an all-time high, and really no affect of inclusion or exclusion of coastwide biomedical mortality. Just for a direct comparison, because everybody got used to the Virginia Tech Trawl Survey and the swept area estimate of abundance being the way that we assessed the horseshoe crab. This graph just shows how to do a direct comparison to the Virginia Tech Trawl Survey here in gray, and then the Catch Multiple Survey Analysis in black, in the black dash line. You would see in the few most recent years our analysis, they line up very, very closely between Virginia Tech and the Catch Multiple Survey Analysis. There are some years where the CMSA was higher, some years when it was lower than the Virginia Tech estimate. This is the same comparison, the CMSA in black and the Virginia Tech Trawl Survey in gray for the male horseshoe crab abundance.

It's interesting that in the most recent years the Virginia Tech Survey actually gave us a higher abundance estimate than what the CMSA does. But they are still, both of them are at their highest levels in the most recent year. Taking this information, we then can make a harvest recommendation based upon the current state of the system, so that means the abundance of male and female crabs along with red knots.

Coming out of the ARM Framework and our optimization we have what were known as harvest policy functions. These harvest policy functions then allow us to take the abundance of both species, and recommend an optimal harvest. AS per Addendum VIII, the recommended harvest is then rounded down to the nearest 25,000 crab.

This is in an effort to protect confidential biomedical data, because if we put out the exact population estimate, somebody could work backwards and essentially solve for what the biomedical harvest was in Delaware Bay.

### **SET 2024 SPECIFICATIONS**

DR. SWEKA: For 2024, the recommended harvest coming out of the ARM Framework would be 500,000 males and 175,000 females.

This is based off 39,800 red knots in 2022, approximately 16 million female horseshoe crabs, and approximately 40 million male horseshoe crab. When we then take these harvest recommendations and apply the allocation scheme that was part of the Addendum VIII, and also maintain, you know we partitioned horseshoe crab based on their proportions are actually Delaware Bay origin, and also institute an Addendum IV cap for Maryland and Virginia.

These are the harvest quotas that would ultimately result for 2024. You can see of Delaware Bay origin, you sum the crabs up across the state, 500,000 males, 175,000 females. For the total quota, it's slightly more with 513,000 total male and 185,000 total female. With that I can take any questions on the 2023 results and the 2024 harvest recommendations.

CHAIR CLARK: Before we take those questions, I'm going to turn it over to Caitlin to put up a couple slides.

MS. CAITLIN STARKS: Just to start the conversation off for the Board's consideration today is to set the 2024 Delaware Bait harvest specifications. I just provided this as an alternative as well, considering what was approved last year. This is here as well, if it needs to be used or discussed.

CHAIR CLARK: Thank you, Caitlin, and with that we'll take questions for John, or comments about the harvest specifications. Any questions? Okay, I'm not seeing any, oh, Shanna Madsen.

MS. SHANNA MADSEN: I was seeing no questions, so I was prepared to make a motion.

CHAIR CLARK: Very good, in that case, go right ahead, Shanna.

MS. MADSEN: All right, I'll wait for a second, because I know I've got it up there. The motion is **move to accept the 2024 Adaptive Resource Management harvest specifications with 500,000 males and no female harvest on Delaware Bay-origin crabs. In addition, the 2 to 1 offset will be added to Maryland's and Virginia's allocations due to no female harvest.**

CHAIR CLARK: Thank you, Shanna, do I have a second? Craig Pugh seconds. Any discussion on the motion? Shanna, did you want to say anything about it?

MS. MADSEN: Sure, yes, I can make a couple of comments on the motion. My justification for making this motion is similar to the one that we made last year. You know I think that we've heard from the public that right now there is not an appetite for female harvest, so the Mid-Atlantic states have decided to continue utilizing the offset, and only having male harvest.

I do think that setting the specifications this way leads very well into our next agenda item, and some ideas that I have moving forward, on how to handle years where we're going to continue to only have male harvest, even though the ARM recommends to us that we can also harvest females.

CHAIR CLARK: Craig, did you have any comments you would like to add?

MR. CRAIG PUGH: Yes, I agree, at this time I know we've explored the female harvest, but it's obvious to us, the people of the state of Delaware really don't want to accept that. They have no appetite for that. This seems to be the most reasonable solution, and we're willing to accept it.

CHAIR CLARK: Any further comments on the motion? I see Joe Cimino.

MR. JOE CIMINO: Thank you, John, for the presentation. I'm encouraged by the recent numbers, but it was a long time getting here, so I fully support this motion, because I think we need to get a few more years under our belt, before we really start seeing stuff. In fact, I know we can't make motions, that we have to revisit this every year and can't make a motion for no female harvest into the future. But I certainly hope that others around the Board would support that until we see this positive trend increasing for a fair amount of time.

CHAIR CLARK: Thanks, Joe, and I think that will probably segway into a topic we'll be touching on. But for the meantime, because I don't see anymore hands, are there any hands online? None online, so in that case I don't think anybody needs to caucus. Is there any need to caucus? Seeing none; why don't we try doing this the easy way.

**Is there any objection to the motion? Seeing none; the motion is passed by consent.** Before we leave this topic, anybody want to talk about the specifications going into the future? Okay, we'll get back to that after we talk about the results of the survey.

#### **CONSIDER RESULTS OF STAKEHOLDER SURVEY ON DELAWARE BAY MANAGEMENT OBJECTIVES**

CHAIR CLARK: I'm going to turn it back over to Caitlin, to cover the stakeholder survey.

MS. STARKS: I'm going to try and go quickly through this given the time. I hope you all had a chance to read the report. But in this presentation, I'm going to cover the background on the survey, the methods used, the results and then talk about next steps. To start, the ARM Framework was established back in 2013, implemented in 2013, and that has been used to set bait harvest specifications for horseshoe crabs of Delaware Bay origin, with consideration of abundance of horseshoe crab and red knots.

That was peer reviewed in 2020, the revision was peer reviewed in 2021, and approved by the Board

for use in 2022, and officially adopted for setting Delaware Bay specifications under Addendum VIII. During the public comment process for Addendum VIII, the public expressed significant concerns and over 30,000 comments about the status of the red knot population in the Delaware Bay and the potential impacts that could have with the limited female harvest that was allowed for under the revised ARM.

In light of those concerns, the Board set the 2023 specifications with 0 females and using the 2 to 1 offset. This May, the Board discussed approaches for evaluating the current goals and objectives for the Delaware Bay horseshoe crab fishery and ecosystem, and they decided to form a workgroup to develop a survey that would be distributed to stakeholders of the region, including bait harvesters and dealers, biomedical fishery and industry participants, and environmental groups in the Delaware Bay Region.

The purpose of the survey was to provide the Board with information to help them evaluate this current management objectives. The workgroup met four times in June through September, to develop the survey. These are the overarching questions that the group aimed to get insight into through this survey.

A key question that could help inform management is whether or not there is demand for the harvest of female crabs in the fishery. Knowing that many feel female harvest should not be allowed at present from those public comments, what are the conditions that would make stakeholders comfortable allowing female harvest?

What management goals for the Delaware Bay Region are important to stakeholders, and ultimately, should the Board consider changes to the management program for the Delaware Bay bait fishery. The survey was developed by the workgroup and reviewed by a social science researcher, to improve the questions and remove sources of bias.

The workgroup then identified a pool of

stakeholders from the Delaware Bay states of New Jersey, Delaware, Maryland and Virginia, collected their contact information, and were able to send the survey out to 107 individuals through Survey Monkey at the end of August. The table here is showing the numbers of stakeholders in the target stakeholders' group and state.

Now I'll move on to the results. We had a 38 percent response rate to the survey, with 40 responses. The largest numbers of respondents were from New Jersey, and the largest number for primary field of work were from commercial fisheries. As you'll see later, the groups that were identified from their responses in Question 2 about field of work, were used to break out the responses to some of the later survey questions, to see how the stakeholder group responded. Additionally, the commercial fisheries group was administered a specific set of questions that were aimed to get a better understanding of the fishery, and the perspective of the commercial industry. First the commercial fisheries group was asked what the horseshoe crabs they harvest or sell are used for.

Most said bait or both bait and biomedical, and one said they did not know. Fourteen respondents also said they have harvested female horseshoe crabs in the past, and five had not. When asked how important it is to be able to harvest or sell female horseshoe crabs for bait in the future, the majority said it was very important, and the next largest group said of average importance, and then absolutely essential, and only two of those respondents said it was of little or no importance to them.

A strong majority of the commercial harvesters or dealers also agreed that female horseshoe crabs are worth more than males, and similarly a strong majority disagreed with the statement that there is no market demand for female horseshoe crab. When asked to choose between two quota scenarios, one where they would have a larger overall quota of only male horseshoe crabs, and another where they would have a smaller overall quota, including some female horseshoe crabs, there was an even split in the responses.

When you look at them by state, you will see that the respondents from New Jersey tended to the majority prefer the larger overall quota, but respondents from Virginia all preferred the smaller overall quota, including females, and there were insignificant trends in the other states. That was the end of the slides that were administered only to the commercial fisheries group.

The rest of these were applied to all of the survey responding. These next few slides are showing the results of Question 8 in the survey, which asks participants to respond to six statements about different components of the Delaware Bay ecosystem, with their level of agreement on a scale of one to five, where one is strongly agree and five is strongly disagree.

On this slide are the results to two statements, the first is the Delaware Bay population of horseshoe crabs is healthy, and the that's on the left. Then on the right the number of horseshoe crabs in the Delaware Bay population is increasing. The general thing to note with these graphs is how the responses are distributed for each of the respondent's groups, which are shown as different colors in those bars.

For some groups the answers are generally similar among all the respondents in that group, but in some cases, there is not as much agreement, and those responses are more spread out. One challenge that is to be noted for all of these questions, is that we don't have equal numbers of respondents in each of those groups, and some of those groups did not have very many respondents, so that makes it difficult to look at those trends.

These are the responses to the statement the horseshoe crab bait fishery is negatively impacting the Delaware Bay population of horseshoe crab on the left, and on the right horseshoe crab bait fishery is negatively impacting red knots in the Delaware Bay. Then these are responses to fishermen should be allowed to harvest female horseshoe crabs from the Delaware Bay population if it is at a healthy level, and fishermen should not be allowed to harvest male horseshoe crabs from the Delaware

Bay population if it is at a healthy level. When you look at the average response to each of those statements by group, which is what's shown in each cell of this table, you can see that there is a lot of disagreement between groups on each of the statements. In this table, the cells are color coated with the averages that fall on the side of agreement shaded in green, and the averages that fall in the side of disagreement shaded in red, and averages that are more in the neutral range are white.

You can see as it alternates back from green to red to white to green, there is not a lot of agreement going across a row with each individual statement by each group. The next two questions were focused on the perception of different impacts on the horseshoe crabs and red knots. Here we see that of climate change, horseshoe crab harvest and human development of the shoreline.

The average response from these individuals they ranked to be human development of the shoreline as having the greatest impact on the Delaware Bay population of horseshoe crab. That is again the average of all responses. It should be noted that some of the group responded differently, so the respondents in the environmental group and the academia or research group ranked horseshoe crab harvest as having the greatest impact on the horseshoe crab population. Then the pattern in the results for the second question are quite similar to the last.

When they ranked the impact of these three things on the red knots that stopover in the Delaware Bay, so we ranked climate change, reduced egg availability due to horseshoe crab harvest, and human development of the shoreline by the level of impact. The environmental and academia group both ranked reduced suitability due to the horseshoe crab harvest as the highest impact, and the commercial fisheries and biomedical groups ranked human development of the shoreline as having the highest impact.

The next set of questions focused on the importance of different management objectives to the respondents. First, they were asked how

important each of these seven items on the left were on a scale of one to five, from not important at all to absolutely essential. When all of the responses were averaged, that is what is showing in this bar graph. The two most important issues were using the best available science to inform management and maintaining a healthy population of horseshoe crab.

Again, it should be noted that there were differences when this is broken out by groups. To test this question another way, the responses were also asked to rank the first five of those objectives by their importance, and in this case the results more distinctly show the pattern where maintaining a healthy horseshoe crab population is on average the most important of the five objectives.

This matrix shows that the breakdown from that last question, when the responses were averaged by group. Green is indicating a higher rank was assigned, on average. Red is indicating a lower rank was assigned on average, and yellow is an average that falls more in the middle. You can see here that three of the five stakeholder group on average, ranked maintaining a healthy horseshoe crab population as most important. There was a tie for the biomedical group with allowing horseshoe crabs to be used in the biomedical industry for human health. Then three out of five groups on average ranked maximizing horseshoe crab bait harvest as the least important objective. Then protecting female horseshoe crabs ranked in the middle for four out of the five groups, based on group average. But the rank of the other two issues were less consistent among the group.

The next question was asking the respondents if the ARM model should be modified, and of the 36 responses, 47 percent said yes, 20 percent said no, and 33 percent said, I don't know. The respondents who answered yes to this question were then presented with another question, which asks why they think it should be modified, and 16 open-ended responses were given to this.

There was a wide range of responses, but among the commercial fishery members who responded,

there was a theme that stuck out, which was the idea that the ARM is underestimating the number of horseshoe crab. Then seven responses, mostly from the academic or environmental conservation respondents spoke about issues with the model and built in assumptions in the framework.

Then two comments stated that the horseshoe crab population should be large before the harvest is allowed to be increased. Question 15 then asks survey participants if they think a limited amount of female horseshoe crab bait harvest should be allowed at this point in time, and 35 responses, we had and 49 percent said yes, 37 percent said no, and 14 percent said, I don't know.

This graph is showing how the responses were distributed within each group in the chart. This next question aimed to understand the stakeholder opinions on whether female horseshoe crabs should be collected for biomedical purposes, and again we had 35 responses, 46 percent said yes, 43 percent said no, and 11 percent said, I don't know. Again, the trends were different in how the numbers of each of those groups responded as shown in the graph.

Then the last question in this survey was an open-ended question, and it provided an opportunity for the respondents to add information that might not have been considered in the other survey questions. They asked, what you think is the most important, what is most important for managers to consider when making decisions about the management of the Delaware Bay horseshoe crab population.

The more prominent themes in the responses about what is most important were the health of the horseshoe crab population, basing management decisions in robot science, allowing sufficient bait harvest, and impacts on fishermen in coastal communities. Then some other mentions included the larger ecosystem as a whole. Allowing for biomedical use, switching to synthetic alternatives to LAL and bait, and making sure there are adequate spawning beaches, and improving the data that are used for management.

To wrap up, I have summarized some of the key takeaways from the survey that respond to the overarching questions posed by the workgroup. First, the commercial industry respondents did show with their responses that there is demand for female horseshoe crabs, and they are considered more valuable than males. The majority of the commercial industry respondents also thought female harvest should be allowed now, but the majority of other respondents did not. Maintaining a healthy horseshoe crab population is considered one of the most important goals across the stakeholder groups, and many of the respondents do think the current ARM Framework should be modified, but there are varying reasons behind that option or opinion. Lastly, in general, stakeholders highly value the use of the best available science to inform management. In response to the survey results. If the Board wishes to consider any next steps moving forward, these are a few potential paths. The Board could task the workgroup with going back and developing additional recommendations based on these results.

The Board could also direct staff to conduct a more in-depth process involving stakeholders from these various groups, like we outlined when we proposed the options for investigating this issue. If the Board does want to make a change to the management program that was established under Addendum VIII, then a new addendum or amendment would be required. With that I can take any questions.

CHAIR CLARK: Thank you very much, Caitlin, I think the survey did a great job of confirming what we suspected the different groups think about this. Before we get further in the discussion, I just wanted to acknowledge the phenomenal amount of work that Caitlin put in to bring this survey together, get it out, and compile that great report. Very much appreciated, Caitlin. With that do we have any questions or comments about the survey? I see Dan McKiernan, go ahead, Dan.

MR. DANIEL MCKIERNAN: Caitlin, is there any explanation for why females horseshoe crabs are considered more valuable?

MS. STARKS: The survey did not address that question.

MS. MCKIERNAN: Is there anyone in the room who could?

CHAIR CLARK: Dan, the horseshoe crab, well, Craig can get that. But I think it will be about eels, right, Craig?

MR. PUGH: Well, it's not just the eels. The female horseshoe crab is used for bait for conchs, catfish and eels as well. Where your most marketed difference is in landing is when the female horseshoe crab was eliminated in American eel landings. I know that they consider that as depleted resource, but for most of us that fished it, understood why the landings were tremendously lower after they eliminated that from our options.

Anybody that is my age, I consider myself one of the new old guys, and I've said that here before. I'll repeat it again, if you have fished with that, and I would say most of the fellows of that age group would be between 50 to 70, understand, because they've used that bait in the past, and they know that there is nothing comparable to that bait for that type of fishery.

It works better than anything else that is out there. You know trial and error, there is no artificial bait that can even match it, not touch it. It would be like putting a piece of sandpaper in there, anything else other than that. It is that extreme in its catchability, especially when they are producing eggs. Even the frozen, we used to freeze them, cut them, harvest them, pack them, freeze them up for bait, so that we could use them through the winter and fall months as well. Because of that their value was well over 100 percent of what the male was, and much, much well over any artificial bait that you could ever imagine. But yet, it was a huge resource for us that was taken away about 20 years ago or so. In saying that and giving you what my age is, some of the newer fellows that are in our fisheries that are in their 20s, in their 40s, have not experienced that.

They don't know the catchability of that product and what it will do. Their standards are a little lower than ours because of that, but value wise, yes, without a doubt. It was highly prized, highly valued. But I think as our groups of fishermen age out, it looks as though the appetite for this is somewhat extinguished.

CHAIR CLARK: Thanks, Craig, and I confirm what Craig said there. The year after females were banned in Delaware, from 2007 to 2008, our eel landings dropped by 50 percent. It really is an amazing bait for eels in the Delaware Region. Mike Luisi, and then Shanna.

MR. MICHAEL LUISI: I also wanted to acknowledge Caitlin's hard work. You stole the words out of my mouth, as Chair. Being part of the working group, not only was it amazing to watch Caitlin put together the survey, but to deal with the five or six of us was another challenge all of its own, whether tracking us down or dealing with John, Mr. grumpy.

You know, you can't find him and then he's grumpy about things, so Caitlin did an amazing job. I do want to say and I do want to say this for the record, and I've made this point a number of times before, in regard to the female horseshoe crab harvest for bait. I don't know how many years it has been now, but we slowly went from a female crab majority of the harvest down to a 50/50 down to a 2 to 1, down to nothing, as far as female harvest in Maryland.

I don't want the Board to get the impression that there is no interest in the female crab for harvest and for use of bait, it's just that the fishermen right now, given the amount of interest in the topic of horseshoe crab, shorebirds and other things, would just rather leave things alone. Although they would make more money, and probably for eels and conch pots, would probably do a little better if they were able to buy and sell the females.

I just wanted to make it clear that there is an interest there, and I don't know what the best word is, but the drama around it is more than what the fishermen are willing to deal with, so they would rather just make use of what they have with the

males. I think in moving forward, if we're taking this survey and thinking of it as giving us a push towards next steps. I think there should be something, if a modification to the ARM is the way we go.

There should be something there so that when the modeling is telling us that something is allowed to be harvested sustainably, that it's not a fight, it's the best available science. This is what it's telling us we can do, and that next level of argument would be unnecessary, and maybe our fishermen, if the populations of the birds and the crabs were high enough, would be able to benefit from that.

CHAIR CLARK: Shanna Madsen.

MS. MADSEN: I have a question for, I guess the dynamic duo, as you called them, Dr. Sweka and Anstead. I want to preface this question with saying that the reason that I'm asking it is not because the ARM "sucks." It's because I have a question regarding what we could potentially consider moving forward. I would like to know if the ARM team or the Assessment Team has started to consider any modeling approaches or information that you could give the Board, if we continue to decide to only harvest males.

DR. SWEKA: We haven't really discussed it formally amongst the ARM Workgroup. I certainly have a few ideas that if we're going to continue with male only harvest, essentially the process could be a lot simpler, and rely on a lot less data. But again, there is the conversation. You know I have some thoughts. They haven't been discussed with the entire committee or with other stakeholders yet.

CHAIR CLARK: Further questions, discussions? Okay, I believe at this point, is there anybody online, Caitlin? Okay. Do you want to put the slide back up that had possible actions here for this, Caitlin? Caitlin outlined the next steps, and Shanna, you have a proposal.

MS. MADSEN: Yes, I actually have a motion prepared, which is in essence bullet point 2, which Caitlin has up on the screen, and I'll wait until the

motion gets up and I will speak to it. Okay, great, thank you. My motion is, **move to use the Stakeholder Survey Report as a basis for a Horseshoe Crab Management Objectives workshop, which would include a small group of managers, scientists, and stakeholders to explore different management objectives for the Delaware Bay-origin horseshoe crabs.**

This workshop should focus on multi-year specification setting and modeling approaches when selecting no female harvest. The intent would be to provide a report to the full Board in time for the 2025 specification setting process.

CHAIR CLARK: Thank you, Shanna, do we have a second? Joe Cimino. Would you like to speak to the motion, Shanna?

MS. MADSEN: Sure, thank you, John. I would also like to echo my big thanks to Caitlin. I think that the survey was definitely the correct move forward. However, the results of the survey lead me to believe that we definitely need to start to have more open conversations about what our management objectives should be. If we are not going to continue to harvest female horseshoe crabs, I think that the Delaware Bay states have had conversations.

Like Mike just commented, it's not that our harvesters don't wish to harvest females, or don't have a market for harvesting females, but at the time right now, you know the public is very interested in us not moving forward with harvesting females. In that case I think it's incredibly important for stakeholders, managers and scientists that have an interest in this Delaware Bay origin stock to have a discussion on what our management objectives should be, and find those.

They are going to oftentimes be conflicting, but make that determination on what we do when we don't harvest female crabs, and hopefully can move forward in a multi-year specification setting process. The Board can make a decision, hopefully ahead of time, as to the period of time that they would like to select, not harvest female horseshoe

crabs and move forward with that. I think that this really mirrors what we did for Atlantic menhaden, and that turned out incredibly well. It was really, really helpful to have everyone in the room discuss how to move forward. I look forward to hopefully getting this process up and going, if the Board agrees.

CHAIR CLARK: Joe, did you have anything you wanted to add to that?

MR. CIMINO: Just quickly. I think unfortunately we're saying that impact of climate change progressing possibly faster than we thought. Certainly, we're at a level far beyond what we experienced when we first started this process. I am proud of this process, and I just think this is a next step forward for it.

CHAIR CLARK: Do we have further discussion of this motion? Anybody have anything you would like to add? Not seeing any, is there any need to caucus? Not seeing any, let's see if we can to this the easy way again. **Are there any objections to the motion from the Board? Not seeing any; the motion is approved by consent.**

#### **CONSIDER APPROVAL OF FMP PLAN REVIEW AND STATE COMPLIANCE FOR 2022 FISHING YEAR**

CHAIR CLARK: We're going to move on now to Item Number 6, which is Consider Approval of the Fishery Management Plan Review and State Compliance Reports for the 2022 Fishing Year.

MS. STARKS: Again, I'm going to move quickly, to try and make up our time. This is our management history for horseshoe crabs. The most recent edition is of course, Addendum VIII in 2022. Then this figure shows the annual values of reported horseshoe crab bait harvest in orange, and biomedical collections in light blue, and estimated biomedical mortality in dark blue, and values are in millions of crabs.

The total reported bait harvest in 2022 was 570,988 crabs, and this excludes confidential landings from Rhode Island and Florida. The 2022 landings were a



23 percent decrease from 2021, and still well below the Commission's coastwide quota, which is 1.59 million crabs, and the total state-imposed quota, which is 1.03 million crabs.

The states of Delaware, Massachusetts, New York, Virginia and Maryland made up 99.7 percent of the 2022 coastwide landings, with Delaware, Maryland and New York harvesting the highest numbers. Then for biomedical, in 2022 the number of crabs that were selected for the sole purpose of LAL production was 911,826 (my brain is going today) crabs, and this is a 26.8 percent increase from 2021.

The estimated biomedical mortality was 145,920 crabs, and this number includes the observed mortalities reported by each state, as well as an additional 15 percent of the total crabs that were bled and are assumed to die. In 2022 the biomedical mortality represents about 20 percent of the total directed mortality for horseshoe crabs, which is about 717,000 crabs. Compared to 2021, in 2022 the biomedical mortality estimates increased, but the overall total removals, including bait harvest, decreased.

This graph is just showing the total coastwide mortality of horseshoe crabs by year, broken out by bait and biomedical mortality, so you can see the relative magnitude of each of these sources of mortality. For de minimis states, states can qualify if their combined average bait landings for the last two years are less than 1 percent of the coastwide total for the same two-year period. In 2022, requests from South Carolina, Georgia and Florida were submitted, and they meet their criteria for de minimis status. The PRT made a few recommendations based on the review of the annual compliance reports. First, as usual is to seek long term funding for the Virginia Tech Trawl Survey, which is critical data for our current management program. Then they also recommend working towards getting annual estimates of horseshoe crab discard removals.

Then with regard to the state compliance, the only minor issue noted by the PRT is that reports from Massachusetts and Connecticut were not submitted

by the deadline, and other than that all states and jurisdictions appear to be in compliance. The PRT recommends approval of the state compliance reports, de minimis requests and the FMP review for the 2022 fishing year. I'll take any questions.

CHAIR CLARK: Any questions for Caitlin about the FMP review? Roy Miller.

MR. ROY W. MILLER: Caitlin, do we have any information on what percent of the biomedical take and/or mortality are female horseshoe crabs as opposed to males?

MS. STARKS: We do. It would take me a minute to track down the numbers of male and female percent for the biomedical mortality. That's what you're looking for? Okay, I can look that up.

CHAIR CLARK: Okay, while Caitlin is doing that are there any other questions about the FMP review? Seeing none; in that case, would somebody like to make the motion to approve? I have Mike Luisi.

MR. LUISI: Is there a motion?

CHAIR CLARK: Do you want to go ahead?

MR. LUISI: I'm part of the new/old, I'm getting close to the new/old.

CHAIR CLARK: Can you read that, is it big enough?

MR. LUISI: Of course, it is, John. **Move to approve the FMP Review, state compliance reports and de minimis requests for South Carolina, Georgia and Florida for the 2022 fishing year.**

CHAIR CLARK: Okay, we have a motion is there a second? Emerson Hasbrouck. Is there any discussion of this motion? Seeing none; **is there any objection to this motion? Seeing none; the motion is approved by consent.** Caitlin, you have the numbers for Roy?

MS. STARKS: I hope so. I have a massive spreadsheet, and I believe that in 2022 the males collected were 43.9 percent and the females were

34 percent, and the rest were unknown.

CHAIR CLARK: Okay, we finished Item Number 6.

### **REPORT ON STATUS OF SYNTHETIC ENDOTOXIN TESTING REAGENTS**

CHAIR CLARK: Now we are on to the Number 7, which is Report on the Status of Synthetic Endotoxin Testing Reagents, and that is Caitlin also.

MS. STARKS: Give me one moment to catch up. All right, so I want to start off by saying that I'm obviously not an expert on this subject, but at the last meeting the Board requested a speaker from a nonbiased third party, like the FDA. I am not the FDA, but we did reach out and we weren't able to find a speaker for this meeting, so I pulled some information together and did my best to gather what might be helpful.

For some quick background. LAL has been used to detect pathogens from endotoxins in patients and medical devices and injectable drugs for over 40 years, and it's currently the standard endotoxin test in the U.S. As you all know, there has been building public interest in transitioning to synthetic tests in the U.S.

Alternatives to LAL that are not derived from horseshoe crab blood directly, they have already been developed, they are called Recombinant Factor C (rFC) and Cascade Reagents, which is (rCR), and these are available for use in the U.S., but they are subject to additional testing every time they are requested to be used., to validate that they are comparable to using the LAL test.

Part of this is related to the standards that are set by the U.S. Pharmacopeia and I'll state USP for short. This is an independent scientific nonprofit organization, and its purpose is to set standards for healthcare products in the U.S., collect information on those and disseminate it to providers and consumers on using the products.

The USP standards have legal recognition in the U.S. and they are also used in many countries around

the world. At this time in the U.S., my understanding is that the two recombinant endotoxin tests (rFC) and (rCR) are considered alternative methods to the LAL test, and that means that using them requires demonstration that they are comparable to the LAL test for each and every product that they would be used for.

Recently, though, the USD has proposed adding a chapter to their compendium that would specifically provide standards for the use of these two recombinant tests, and as supposed under those standards that are in this new chapter, it would mean that moving forward if a manufacturer wants to use one of these two tests on the new biopharmaceutical products, that it would not require the comparability validation that is currently required.

However, for products that are currently being tested with LAL, they would need to demonstrate comparability in order to switch over to using the synthetic test. In summary, what I think this means is that if the proposed USD chapter is adopted by the Pharmacopeia, it would open up a pathway for more use of (rFC) and (rCR) in the U.S. and there may be additional requirements from the FDA related to its use, but it is a step forward.

It's clear from their information that it wouldn't mean that LAL would go away. It just means that manufacturers would have more options that are more easily accessible to that. This is a proposed chapter, and it has a comment period that will be open from November 1 through January 31, 2024. I can attempt to answer questions, but again, I'm not an expert, so I can always just write them down and bring answers back with it.

CHAIR CLARK: Thank you, Caitlin, very interesting. Just one thing that I wasn't clear about. Are (rFC) and (rCR) pretty much do the same thing? I mean are they like Coke and Pepsi?

MS. STARKS: Yes, my understanding is they are just different genetic combinations.

CHAIR CLARK: Okay, great. Are there any questions

for Caitlin about the LAL and the synthetic endotoxins here? Oh, I see Dr. Rhodes in the back there.

DR. MALCOLM RHODES: Yes, I'm afraid I'm the one that brought this up at the time, because we did have a presentation quite a while ago where they were talking about these new combinations being used. This information is interesting, but it's basically just saying, if you want to change from the gold standard you have to prove it's as good as.

We haven't learned what the, as good as is. Maybe it is Coke and Pepsi, and we're dealing with Coke, which I still think is number one, and want to know if Pepsi is going to be as good as. I think the problem, if you're trying to look it up. There is lots of information about the recombinant testing agents, for want of a better word, that they tend to come from the industry, and you know each one is going to have their own bias about it, which would be the hard part.

At some point, and like I said at the meeting before, it might be a year from now, if we could get someone from NIH or a PharmD possibly that could come in and kind of explain the process and where we are. I mean it's great where we're at, but as far as I know, most drugs are still LAL. Every vaccine that is used in the United States, LAL is what is used to prove its safety, that it has no endotoxins in it at this point.

Just for our knowledge, since frequently every letter we get says, well why are you all still using this when there is a safe alternative? You know as far as I've read, it probably is, but probably isn't safe enough for the public, when we're talking about health concern. That is why I would like to see if at some point, you know we could get someone.

I would think it would probably be when we're in Washington, where we could get someone from one of the branches. I know how impossible it might be to do, but you know I would love to talk to you at some point, and see if we could get kind of, this is what it does. Because when you read about the specific tests, there are certain ones that have

problems with drugs that have proteases, and some with glutens, and they have shortcomings, as does LAL.

But you know LAL is a huge step above the rabbit test that was before that. I won't go on and on about it. But you know, I appreciate getting that to this page, but it's more about, well, if you can prove this and you don't have to use it, as opposed to, is this as good as, which was what I was hoping for?

CHAIR CLARK: Thank you, Dr. Rhodes, it's a complicated issue, isn't it. We have a couple of online commenters. First up is Allen Burgenson.

MR. ALLEN BURGENSEN: Good afternoon. My name is Allen Burgenson, and I am an author of several of those papers that folks have been discussing. One thing about recombinant Factor C and R, the r test aids, it's not Coke and Pepsi, it's Coke and lemonade, both satisfy your thirst but using different mechanisms, (rFC) it's just the recombinant of the detention protein, with a different measurement. It uses light, whereas the (rCR) also has the same enzyme system that LAL does, the complete cascade.

But it yields a turbidity or a chromogenic result. Now one thing that I published back in March of this year was in the Pharmacopeia Forum, which is the official journal of the United States Pharmacopeia, was a comparison of two standard LAL products against two of the (rFC) products. One thing to note, and folks have to understand, all the reagents don't work the same on every time.

In my study I showed that some reagents underpredict the amount of endotoxin in a sample, and this is natural endotoxin from a water system, which is what would be contaminating your products. Your product is not contaminated with the standard, which is known as RSE or reference standard endotoxins, or controlled standard endotoxin.

If you have either one of those in your product, you don't have contamination you have sabotage, because those two don't exist in nature. What does

exist in nature is what is in your water system. I published a study using four different drugs and four different kits, and in some instances the recombinant product underpredicted the amount of endotoxin in a drug by more than a twofold, which means nothing if you are testing down around normal processing.

Very low levels of endotoxins, plus or minus a twofold is negligible. However, when you are up around the endotoxin relief level, or if you're testing at the maximum valid solution, which is the most you can dilute and still detect the endotoxin, and you have a plus or minus twofold difference, and you're underpredicting the amount of endotoxin by more than a twofold, then there is the potential health issue.

It concerns me that the USP has said that all new biopharmaceuticals, if this chapter is approved, do not have to do the comparability, because that is the most dangerous part right there. The company may recover their PBC spike, I'm sorry, I'm over time.

CHAIR CLARK: Thank you, Mr. Burgenson, that was very interesting. I think that gets to some of what you brought up, Dr. Rhodes, about that. Appreciate that, and we have another online commenter, and that is Joe Gresko. Go ahead, Joe.

MR. JOE GRESKO: Just a quick follow up to the Doctor's line of questioning, and to be clear, the synthetic alternatives would need to be validated by the FDA, right?

CHAIR CLARK: Is that true, Caitlin?

MS. STARKS: I am not an expert, again. I don't know if we can answer that question with certainty.

MR. BURGENSEN: I can answer that if you want.

CHAIR CLARK: Is that a, no? It just has to be done by USP, not FDA?

MR. BURGENSEN: No, it's done by the individual end user, the individual pharmaceutical company

on a per product basis. They have to do the side-by-side comparisons and validate it, and then submit that validation data to the FDA, in the form of a regular FOIA application. The individual end user, the individual pharmaceutical company has to do the validation.

CHAIR CLARK: Thank you, thank you very much, Mr. Burgenson. I think that concluded that. Okay, I'm sorry, we have another online commenter, that is Karen Hedstrom. Go right away, Karen.

MS. KAREN HEDSTROM: Yes, thanks, I was late getting in there. I was just trying to gather my thoughts. Is it the Eli Lilly Company already has some products on the market that are using the (rFC) instead of the LAL? Can anybody, you know one of the doctors, comment on how they got to the point that they're at?

I understood that companies could independently pay for their own validations, but with the USP now is advancing to do is to actually take on some of that validation, and of course some of the cost of it, to allow companies that want to go down the route of using the synthetic, to just make it a little bit more viable for them to be doing it, economical and otherwise. Can somebody comment on that? Thank you.

CHAIR CLARK: Thank you, Karen. I don't know that we have anybody here that could answer that, but we will be returning to this issue in future meetings, I believe, so we will definitely be looking to get answers to that and other questions.

#### **REVIEW AND POPULATE ADVISORY PANEL MEMBERSHIP**

CHAIR CLARK: In trying to save time here, let's move on to our next item, which is to Review and Populate the Advisory Panel membership, and Tina, do you have that ready?

MS. TINA L. BERGER: I do, thank you, Mr. Chairman. I offer for the Board's consideration and approval the nomination of Sam Martin, a commercial mobile tending gear fisherman from Maryland.

Sam’s nomination form said that he was convicted of a felony. That is an error, and that was validated by the state, so simply ignore that. But I offer it for your consideration.

CHAIR CLARK: Mike, would you like to make this motion?

MR. MICHAEL LUISI: I sure can, you can put that back up, I’ll go ahead and read it. **Move to approve Advisory Panel nomination for Sam Martin from Maryland.**

CHAIR CLARK: Do we have a second? Shanna Madsen. **Any objections to this nomination? Seeing none; the nomination is approved by consent.**

#### OTHER BUSINESS

CHAIR CLARK: Okay, that brings us on to Other Business. We definitely have a few items, but first I wanted to clear up, Caitlin, as far as the specifications, are we done with that? Did we want to discuss? I think it was kind of covered in the motion, right? Okay, so we’re done with that. Dan, did you have something else that you want to bring up, because there is an “other business” motion also.

MR. MCKIERNAN: I want to plant a question, it’s a rhetorical question at this point. Maybe we could pick it up at the Policy Board. Are we doing enough around the table as Board members to estimate the use of horseshoe crabs in our various fisheries for other species, such as American eel, and of course whelk, which is not an ASMFC managed species. I would like to pick that question up at the Policy Board. I don’t want to discuss it; I just want to plant a question.

#### RESPONSE TO EARTH JUSTICE/SHOEMAKER HORSESHOE CRAB ARM FRAMEWORK ANALYSIS

CHAIR CLARK: Okay, and then the Other Business item that I spoke of at the beginning of the meeting. I think everybody saw in the meeting materials that there was another item from Earth Justice. They went back to one of the scientists they had worked

for, for the previous analysis of the ARM. This time he was supplied with the data from the trawl surveys, and he had the code, I believe, for the ARM model, right this time?

As you probably saw, he had several criticisms of the ARM that were then turned into a huge press release snafu, and I think there is clearly a debate within our Board, I’m sure, as to whether to respond and how to respond. To kind of kick this discussion off, I would like to turn it over to Bill Hyatt, who I think has a motion.

MR. WILLIAM HYATT: Yes, I do have a motion, and I believe you have it, if you could put it up, please. Very simple: **Move to task the Adaptive Resource Management Subcommittee with preparing a response to the September 2023 review of the ARM Framework by Dr. Keven Shoemaker.**

CHAIR CLARK: I have a second from Mike Luisi, and Bill, would you like to speak to that?

MR. HYATT: Sure. All of you had the opportunity to read Dr. Shoemaker’s analysis in our meeting materials. His analysis is detailed, and it raises some serious questions regarding the ARM model. For me as a Board member, and I suspect from many others around the table as well, it’s difficult to evaluate the credibility of this alternative analysis, without having a response from our own folks, and the folks who have developed the ARM model.

The management of horseshoe crabs is obviously far reaching and complex, that is what keeps us around this table for so long at these meetings. For all these and many other reasons, but particularly, so that we as Board members can better understand these issues. I believe it’s important for the Commission to develop a response to Dr. Shoemaker’s analysis. I’ll add, and I think this speaks to some of the previous discussion on this topic. I’ll add that I doubt that this response will be the end of this discussion, but I believe it’s a very important first step.

CHAIR CLARK: I’m going to ask Mike as the seconder, and then I would like to take it over to

John Sweka.

MR. LUISI: I seconded this, because what Bill said I truly believe in. I think when somebody goes out there, puts themselves out there and criticizes or, not to say that's the only reason we would respond is in a critical way. But if somebody is out there putting information together, expecting everyone to listen, and we don't have the opportunity to debate that. It really ends up a one-sided argument, and there is never any real accountability on the individual or individuals that have put together the document that now has generated what I used before, the drama around the issue. I just think it's a good idea. I think it's something we should do more of with other species that we manage, and that is why I seconded the motion.

CHAIR CLARK: Now I would like to turn it over to John, John and Kristen will have to spearhead the work on this, so take it away, John.

DR. SWEKA: Just a point of clarification if this motion should pass. I would like to remind the Board that Earth Justice also supplied comments from September, 2022, they were very lengthy as well, so just up for discussion. If this motion passes and we are to respond, do we restrict our comments to those from September, 2023, or September 2022 and '23 included?

CHAIR CLARK: Well, from my perspective, John, I think that if you're going to comment, including all I think would be very useful. Any other comments around the Board? Bill.

MR. HYATT: Yes, certainly, my intent was what was included in our September, 2023 for this meeting, meeting materials. In particular, I know that the Earth Justice letters and Dr. Shoemaker's analysis sort of parrot one another. But I think from my perspective, particularly interested in the detail within Dr. Shoemaker's report, as opposed to Earth Justice's cover letters, if you will.

CHAIR CLARK: Conor McManus.

MR. CONOR McMANUS: John, from the two sets of

comments, to what degree is there overlap, or has some of the 2022 comments already been addressed via our work since then, I should say.

DR. SWEKA: Nothing has been addressed to the 2022 comments. With what was supplied in the Board materials, they had their new, recent 2023 comments, and then the 2022 comments tacked on as an appendix. I guess it's all there altogether, but no, as the ARM Workgroup we haven't done anything with those comments or discussed it or made any changes resulting from it.

CHAIR CLARK: Any further comments on this? Shanna Madsen.

MS. MADSEN: I'm certainly not going to oppose this motion, but I do just want to warn that I feel that a lot of the questions and concerns that are in Dr. Shoemaker's paper have also been addressed quite a bit in the minority report, if I remember correctly. I appreciate whatever Dr. Sweka and Dr. Anstead put together for us to review, directly in relation to this 2023 updated report.

But I just want to make sure we don't run down a path of continuously asking our incredibly busy TC and ARM group to make responses to what frankly equates to misinformation. Some of the information already contained in the report we can look at and know that they are incorrectly using some of the trawl information. I just wanted to kind of make that point, to not set a precedent for continuing to chase our tails on some of this information.

CHAIR CLARK: That is a point well taken, Shanna. But this is quite an extreme situation we're dealing with. Roy Miller.

MR. ROY W. MILLER: Quickly in response to Shanna's suggestion. I think that this particular response on our part is in a different category, because Dr. Shoemaker's response I think, is driving the impetus for consideration of additional legislation in one or more states, and therefore, I think it is incumbent upon us to respond to this particular set of comments.

CHAIR CLARK: Yes, it certainly has been resonant in our little state, that's for sure. Joe Cimino.

MR. CIMINO: Just a follow up. I mean for something like this it goes back to something Mike Luisi said about accountability. We had a chance to review the draft, since New Jersey's trawl data was included, noticed that the way it was run in Dr. Shoemaker's model was not comparable to what was used for the peer review assessment or ARM Framework, so we confronted Dr. Shoemaker on that, and he confirmed that he did not use the data in the same.

Not that if he had time he would go back and rerun that. I think you know for this kind of information to be at management level, it would also need an independent peer review, and go through the work. I don't see any other way around that. I certainly don't think it's there. I apologize to John and Kristen for having to do this work, but I think at least some review for the Board's sake will be valuable.

CHAIR CLARK: Are there any other questions, comments? Seeing none; does the Board need time to caucus on this? Seeing no need to caucus, **are there any objections to this motion? Seeing none; then the motion is approved by consent**, and thank you very much, John and Kristen. The ARM has done phenomenal work. We're sorry to put extra work on you, but I think this is important to do. Thank you.

#### **ADJOURNMENT**

CHAIR CLARK: Okay, that was our main Other Business item, and is there anything else to come before the Board? Seeing none; then we are adjourned.

(Whereupon the meeting adjourned at 4:36 p.m. on October 16, 2023)