



Specialists in Endotoxin and Glucan Detection

09 OCT 2023

Atlantic States Marine Fisheries Commission
1050 N. Highland St.
Ste. 200
Arlington, Virginia 22201

RE: Response to survey question

Dear Commissioners,

Associates of Cape Cod, Inc. (ACC) has participated in a catch and release fishery of horseshoe crabs (HSC) in the New England region for nearly 50 years. Although ACC does not participate in the Delaware Bay biomedical collection, we do have a strong contingent interest in the management of this major, proximal east coast fishery. We share the desire for a healthy and sustainable HSC fishery; however, ACC is very concerned about the question in the recently circulated survey regarding limiting harvest of female HSC used for biomedical purposes. Limiting access to this resource creates a slippery slope solidifying the basic concept that a ban on female HSC acquisition might be a good idea and would not result in increased risk in the protection of human health. Limitations in HSC harvests directly impact the production of an assay that is critical to guaranteeing the cleanliness of products produced by global pharmaceutical and medical device industries.

The bait industry is 100% lethal and the leading cause of measurable man-made mortality and should be regulated accordingly. Review of harvest data over the past 23 years indicates that conservation efforts have reduced bait harvest rates and that overall harvest, bait and biomedical combined, and related mortality, is well below the thresholds set by the ASMFC. In addition, the ARM model used for over a decade in the Delaware Bay region has successfully helped to manage HSC fisheries in that area which demonstrates positive and increasing trends in population dynamics.

Current research indicates that the impact of a biomedical fishery is minimal to the animals, and data from the ASMFC clearly demonstrates that the biomedical catch and release fishery has a very small impact on overall mortality.

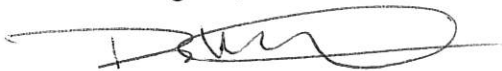
If biomedical harvest were to be limited, it would pose a direct impact to human health. The horseshoe crab blood is used specifically to make *Limulus* Amebocyte Lysate (LAL), which is a product used to detect life threatening bacteria in any injectable pharmaceutical or medical device that enter a human body. Naturally sourced HSC LAL is a key component to endotoxin detection, even though recombinant options are just becoming available, the transition from naturally sourced HSC LAL to recombinant lysate will take at least a decade as regulations, manufacturing practices and customer's risk tolerance catch up with the recombinant technology. Please remember, the FDA will not license any recombinant product including recombinant BET reagent, and the tens of thousands of FDA approved pharmaceutical and medical devices have naturally sourced BET LAL as required reagent. Changing the tens of thousands of FDA approved manufacturing plans will take many years and increase the manufacturing

costs for testing, validation and re-submission of revised manufacturing plans to the FDA. This will increase risks and costs and may even result in the temporary unavailability of certain medical devices and pharmaceuticals.

Conclusion:

Associates of Cape Cod, Inc. commend the efforts of the horseshoe crab ARM subcommittee and the fine work done to stabilize populations of both the horseshoe crab (HSC) and red knots. The relationship between the biomedical facilities and fisheries managers is longstanding and productive. Over 50 years of conservation efforts have proven to be effective as evidenced by the increasing stocks and positive trends in most areas of the limulus range particularly in areas where LAL manufacturers operate. Given the data, it would be reasonable to conclude that biomedical fisheries have little, if any, negative impact on the populations. Prohibiting harvest of crabs of any sex, for biomedical purposes only serves to increase risk to humans by potentially limiting the raw material needed for a critical assay, while having no measurable positive impact to the HSC populations. Thank you for your attention to this most important matter and ask that this material is available for the annual meeting in October 2023.

Best regards,



Brett Hoffmeister
LAL Production Manager