LAL Update

ASSOCIATES OF CAPE COD, INCORPORATED

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Letter From the President

Dear LAL User,

Associates of Cape Cod began 2006 in full gear with the successful consolidation of our product development and manufacturing activities in our state-of-the-art facility located in Massachusetts. We have continued positioning ourselves to better serve your needs by increasing the number of in-house Technical Support and Field Technical Sales Specialists in the U.S. Through our U.K. office and German subsidiary, Pyroquant Diagnostik GmbH, we've expanded our sales scope to 67 countries and made ACC products available worldwide through a network of over 60 distributors. We've added to our core LAL business with the introduction of our Pyrosate® product into the clinical dialysis market, introduced a new line of LAL Reagent water and continue to serve the needs of a growing glucan testing market with our Glucatell® kit. Our Contract Test Services are available worldwide with facilities in the U.S., U.K. and Germany which continue to serve our pharmaceutical and medical device customer needs in the areas of methods development, endotoxin and glucan testing. We also look forward to a mid-year introduction of new software for the Pyros Kinetix® reader, a system optimized for use with our Pyrotell®-T LAL reagent.

In 2006 we will continue to build upon our unique and exclusive glycobiology franchise under our newly branded Northstar™ BioProducts label. To complement the high quality line of Seikagaku enzymes, complex carbohydrates and antibodies, additional product lines from Ludger, Hyalose, IBEX and Selectin broaden our portfolio of glycobiology and carbohydrate chemistry products to support the needs of this rapidly advancing field of pharmaceutical research and development.

We continue to deliver useful tools to the clinical diagnostics field with the recent launch of our Fungitell™ kit and the Beacon Diagnostics™ Laboratory to aid in the diagnosis of invasive fungal infections in critically ill patients. In 2006 we are adding additional sales and technical staff to meet the time sensitive needs of clinicians and their patients.

In this issue of the LAL Update we look at the subject of conservation of horseshoe crab populations, about which there has been considerable publicity over the last 10 years. We are committed to supporting scientifically based conservation measures and take an active role in that process. We recognize that the thoughtful stewardship of the horseshoe crab is a serious responsibility.

Please review our website and new catalog for a whole array of new products and services. Take advantage of our highly respected Technical Support Team and our expert Contract Test Service laboratory staff and let us know how we can help you with your unique testing challenges. We look forward to continuing to serve your needs in 2006.

Sincerely,

A. J. Meuse, Ph.D.
President/CEO

The Population Status of the American Horseshoe Crab, *Limulus polyphemus*

By: ***Michael E. Dawson, Ph.D.***
Director of Regulatory Affairs

Introduction

As an LAL manufacturer, Associates of Cape Cod is dependent upon healthy horseshoe crab populations. In turn, although they may not often think about it in their daily business in the laboratory, everyone performing LAL tests depends on horseshoe crabs for their reagent. Further, throughout the world people unknowingly rely on LAL from horseshoe crabs for the safety of many healthcare products with which they are treated. The great majority of people in developed countries have benefited from the blood of the horseshoe crabs, as have many in the developing world. Over the course of the last ten years, concerns have been raised about horseshoe crab populations in a number of quarters. First to raise the alarm in the 1990's were conservation organizations with a primary interest in birds. Others have expressed concerns for the horseshoe crabs themselves.

Background

The American horseshoe crab, *Limulus polyphemus*, is found on the east coast of North America. The range extends from Canada, down the eastern seaboard of the United States to the Florida Keys and on to the Yucatan peninsula in Mexico. In the Gulf of Mexico, horseshoe crabs are found on the west coast of Florida up to the panhandle. The largest concentration of animals, as well as the largest individuals, is found in the Delaware Bay. In many states, especially those in the middle of the range, there is a significant fishery for horseshoe crabs.[1] Animals are caught for bait, primarily for use in conch (a large sea snail) and eel traps. Horseshoe crabs are also caught by LAL manufacturers for the manufacture of LAL. The

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majority of these are returned to the water alive and survive the collection of some of their blood remarkably well. At the urging of the State of Massachusetts, some of the horseshoe crabs caught for bait are bled by Associates of Cape Cod before they are put into conch and eel traps. This dual-use strategy results in the taking of fewer animals and leaves a greater number undisturbed in their natural habitat.

Horseshoe Crab Populations

The first concerns about horseshoe crab populations were raised by conservation organizations in the mid 1990s, notably the National Audubon Society and the American Bird Conservancy. This was driven by well documented reports of declines in the numbers of migratory shorebirds, particularly in the Delaware Bay. Large numbers of birds stop at the Bay on their northward migration to the Arctic. The stop coincides with the time at which horseshoe crabs spawn and the birds feed heavily on the eggs. Declines in the recorded numbers of spawning animals and in the numbers of eggs counted in beach surveys correlated with the decline in numbers of birds.

In response to these observations the Atlantic States Marine Fisheries Commission (ASMFC) initiated a program to manage the horseshoe crab fishery. The ASMFC is the organization responsible for coastal fisheries (that is fisheries in state controlled waters inside the three mile limit). It is a consortium of the thirteen Atlantic coast states and has enforcement power under federal law. Prior to this, there was no coordinated management plan amongst the various states, and in some states the horseshoe crab fishery was completely unregulated. Initially horseshoe crabs and eels were grouped in a single management board with the assumption that horseshoe crabs would be the less significant of the two species. However, the importance of the horseshoe crab fishery rapidly became clear and a separate board was established. As a result of concerted efforts by fishery officials in a number of states, particularly those bordering the Delaware Bay, a fishery management plan was published in 1998. The plan collated a great deal of information about the species but noted that there was little reliable data available on horseshoe crab populations. The plan also called for a conservative, risk averse approach to the management of the horseshoe crab fishery. Amongst other requirements, the plan required collection of horseshoe crab catch statistics by all of the member states.

Based upon catch data, the so called reference period landings (RPL), individual state quotas for the bait fishery were set at 75% of the RPL. This was finalized in Addendum I to the plan. All states (eventually) met this requirement. Quotas for Delaware, Maryland and New Jersey were further reduced in Addendum III. The management plan, the addenda and other information about horseshoe crabs is available on the ASMFC web site (www.asmfc.org).

The biomedical fishery for LAL manufacturers was exempted from harvest restrictions. This was because animals were returned to the water and the mortality associated with the fishery was recognized as being low. Published estimates of mortality are around the 10% figure.[2,3] In a detailed study of a major Cape Cod population, it was concluded that the effect of the biomedical fishery was minimal.[4] However, reporting requirements were stipulated and if the mortality from this activity rises above a specific threshold, the plan provides for reevaluation.

As a result of the bait harvest restrictions, the cost of bait, and the publicity given to the fishery, the efficiency of use of horseshoe crabs for bait has increased considerably over the past ten years. This effort was given substantial support by ERDG (the Ecological Research and Development Group, www.horseshoecrab.org), which engaged in a program to develop and test bait bags, in which a portion of a horseshoe would be used to bait a trap ("pot"), as opposed to using a whole crab. After successful trials, ERG distributed large numbers of bags on the east coast and especially in the Delaware Bay area. Other developments have recently taken place here in Massachusetts where perforated cups have been successfully employed by fishermen. These measures increase the life of the bait in the pot and so reduce the numbers of crabs used.

Another proposal in the first Addendum to the ASMFC management plan was that a horseshoe crab sanctuary be established in Federally controlled waters (outside the three mile limit) off the mouth of the Delaware Bay. This suggestion was adopted and in March, 2001, the Carl Schuster Horseshoe Crab Sanctuary was created by the National Marine Fisheries Service (NMFS). The reserve is named in recognition of the work of Dr. Carl Shuster, who may be regarded as the dean of horseshoe crab naturalists. (He is one of the editors of the recent book, "The American Horseshoe Crab"[5], an excellent resource for anyone interested in horseshoe crabs.)

There is much debate over the current status of horseshoe crab populations. However, the ASMFC has concluded that populations are either stable or declining slightly. The status of the population differs by region and even locally. For example, a marked decline in a small population on Cape Cod has been documented[6] as a result of the bait fishery. Because of continued concerns about the population in the Delaware Bay (and about the availability of eggs for migratory birds), a fourth Addendum to the management plan has been drafted for comment. It includes a number of management options, one of which is complete cessation of all bait harvesting in the Bay. The draft Addendum IV also includes two management options that restrict the taking of horseshoe crabs for biomedical purposes in Delaware, Maryland, New Jersey and Virginia. This seems unnecessary in view of the high survival rate of bled horseshoe crabs.

Coast wide bait harvest figures have declined substantially since the late 1990s *(Figure 1)*. Landings approached 3 million per year in the late 1990s and were well below one million in 2004 and 2005. Prior to 1997/1998, the harvest increased sharply, probably due to increased reporting (which was either lax or not required in many states prior to the development of the management plan), as well as to a possible increase in catch. Here in Massachusetts the catch has also declined and is well below the state quota, which was finally set at 25% below the 1999 landings. The State Division of Marine Fisheries has taken an active approach to meeting the requirements of the ASMFC management plan to conserve our horseshoe crab populations.

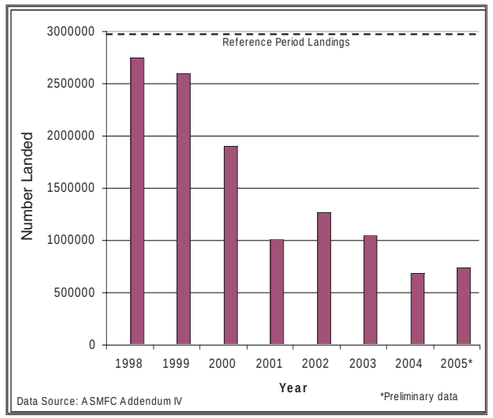

Figure 1. Reported Horseshoe Crab Landings for bait (1998 - 2005)

Conclusion

While there is reason for concern about the status of horseshoe crab populations, especially as the available population data is incomplete, it is clear that the species is not threatened or endangered. The situation is being closely monitored by the ASMFC who are committed to risk averse management of the fishery. Both the populations and the ASMFC are monitored by a number of conservation organizations. Associates of Cape Cod, like other LAL manufacturers, also watch the situation and take part in the process that leads to regulations. We have not had any problems obtaining the horseshoe crabs we need to manufacture our reagents and we do not foresee any problem in the future. All parties involved in the management of horseshoe crab populations are well aware of their importance to human health, to birds, and to eel and conch fishermen. Finally, horseshoe crabs are fascinating animals in their own right and are intrinsic to the Atlantic coast environment. They provoke the curiosity and affection of beach walkers from Maine to Florida. The more respect we give these venerable animals, the less protection they will require.

References

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LAL News and Events

APRIL

REGENERATE
April 24-27, 2006
Westin Convention Center
Pittsburgh, PA
Booth: 110

PDA
April 24-28, 2006
Anaheim Marriot Hotel
Anaheim, CA

PEGS
April 24-28, 2006
Marriot Boston Long Wharf
Boston, MA

MAY

LAL TRAINING COURSE
May 16-18, 2006
Seattle Marriott Sea-Tac
Seattle, WA

JUNE

ASCO
June 3-5, 2006
Georgia World Congress Center
Atlanta, GA
Booth: 4264

IACP
June 5-7, 2006
Washington, DC

LAL TRAINING COURSE
June 14-16, 2006
Falmouth Technology Park
East Falmouth, MA

AAPS
June 18-21, 2006
Boston, MA

SEPTEMBER

LAL TRAINING COURSE
September 19-21, 2006
Gaithersburg Marriott Courtyard
Gaithersburg, MD

ICAAC
September 27-29, 2006
Moscone Center
San Francisco, CA

OCTOBER

IDSA
October 12-14, 2006
Toronto

LAL TRAINING COURSE
October 24-26 2006
Boston Marriott Cambridge
Cambridge, MA

DECEMBER

ASH
December 9-12, 2006
Orlando, FL

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