International Workshop on the Science and Conservation of Asian Horseshoe Crabs

Lonza

Consumer Driven Conservation Initiatives for the TAL/LAL Industry

Maribeth Donovan Janke, Ph.D., Lonza and Glenn Gauvry, ERDG

14 June 2011

Today's Outline

- Consumers of TAL and LAL
- Role of TAL/LAL industry in conservation
  - Two-pronged approach
    - Harvest and husbandry best practices
    - Alternative methods to reduce need for horseshoe crab blood
- Role of TAL/LAL end-user in conservation
- Role of other consumers in conservation

Who are the TAL and LAL Consumers?

- Anyone who relies on the horseshoe crab for their blood:
  - Those who harvest and bleed horseshoe crabs to manufacture TAL and LAL
  - Those who use TAL and LAL to test products for the presence of endotoxin (end-user)
  - Those who rely on safe drugs and devices for health
- Anyone else who impacts the horseshoe crab:
  - Bait fishermen
  - Use crabs for food and folk remedies
  - Affect spawning habitats

TAL/LAL Manufacturers – e.g. Gel Clot Test

- Test sample added to tube
- TAL/LAL is reconstituted
- Small amount put into a tube
- Tube is incubated at 37ºC for about 1 hour
- Tube is inverted
- If the gel stays at the bottom of the tube (as shown), the result is positive for endotoxin

TAL/LAL End-Users - Examples

Pharmaceutical and
Parenteral Manufacturers

Vaccine Manufacturer

Other TAL/LAL Consumers – All of Us

Patient receiving treatment

Children receiving vaccine

TAL/LAL Manuf. Role in Conservation

- To support horseshoe crab conservation, the TAL and LAL manufacturers can:
  - Use best practices in harvesting crabs
  - Use best practices in handling crabs before, during and after the bleeding process (i.e., husbandry)
  - Participate in studies to evaluate industry's impact
  - Develop alternative methods to reduce use of TAL and LAL for endotoxin detection

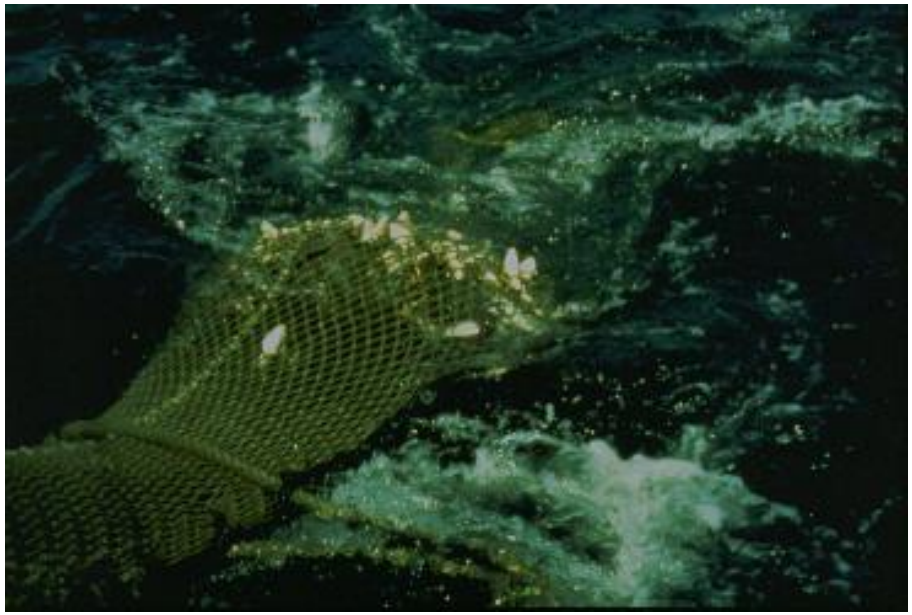
U.S. Harvesting Practices for LAL

- Hand harvest on beaches during spawning season
- Hand harvest in shallow water
- Trawling – harvesting in deeper ocean water
- Use of bait crabs

- With the exception of the bait crabs, other harvested crabs are returned to the water from which they were harvested

Harvesting from the Beach

Harvesting from the Ocean (Trawling)



What is the Best Harvesting Practice?

- In terms of mortality, bleed and release is the best practice
  - Atlantic States Marine Fisheries Commission (ASMFC) uses an estimated mortality rate of 15% for the biomedical use of released crabs
  - Although bait crabs have a 100% mortality rate, bleeding prior to bait use would be preferable to bleeding to death

What is the Best Harvesting Practice, Cont,d.?

- What about harvest method?
  - Harvest method depends on the environment
  - Harvesting from the beach means interruption of spawning activities
  - Trawling means use of fishing net and disruption of ocean floor where crabs are found

Husbandry or Handling Practices

- Once harvested, the horseshoe crabs
  - Travel to the bleeding facility
  - Housed prior to the bleeding process
  - Bled
  - Tagged, marked to assure one bleed per season
  - Stored prior to return trip
  - Returned to the water
- Need to use best practices to help ensure their safe return

Lonza

TAL/LAL Bleeding Process

Lonza

TAL/LAL Bleeding Process

Best Husbandry or Handling Practices

- Bleed conservatively,
  - With the process shown, approximately 50 ml is collected per crab
- Limit amount of time they are out of the water
  - Return to the water within 24 hours is helpful
- Care during the time they are out of the water is important
  - Must keep them cool and moist
  - Important that they do not sit on a dock in hot sun
  - Overnight fishing is helpful (keeps them out of the sun)

Participate in Impact Evaluations

- Annual trawl survey to asses US horseshoe crab population
  - Three LAL manufacturers pledged money to support the 2011 trawl survey
  - Survey designed to sample the horseshoe crab population in coastal waters
  - Provide information regarding population recovery

Lonza

Participate in Impact Evaluations, Cont'd.

- Evaluate harvest and husbandry methods for mortality
  - ASMFC uses 15% estimated mortality for biomedical use crabs
  - Leschen and Correia, 2010, reporting approximately 30% mortality in their study
  - LAL Manufacturers would be well-served by conducting studies that better mimic their specific methods to help estimate mortality and find ways to improve harvesting and handling methods

Why Develop Alternative Methods?

- Currently 4 types of TAL/LAL methods
  - Gel clot
  - Endpoint chromogenic
  - Kinetic turbidimetric and chromogenic
- From the ASMFC 2011 Annual Report
  - In 2010, approximately 550,000 crabs were bled in the United States for LAL
  - “a 24% increase over the average of the previous five years”
  - In the last 4 years, the LAL industry has exceeded the ASMFC recommended mortality limit

Why Develop Alternative Methods, Cont'd.

- Continual increase in harvesting and bleeding of crabs is not sustainable
  - Possible sanctions for LAL industry for exceeding mortality limits
  - Threatened Asian crab population
- To support a decrease in the need to bleed crabs for TAL and LAL, alternative endotoxin detection methods must be developed

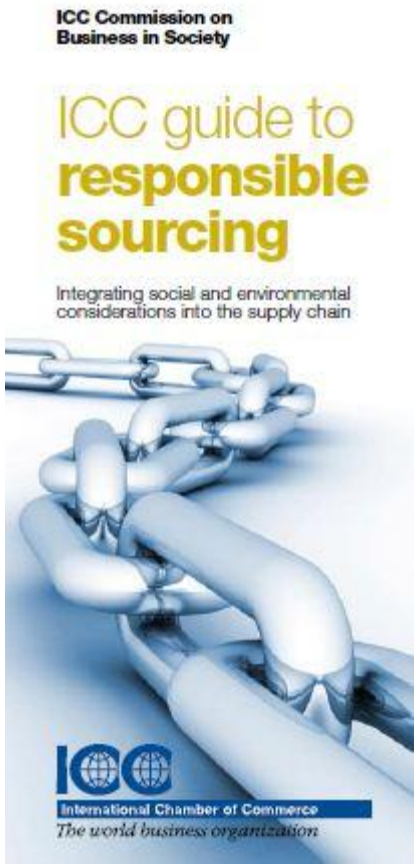
Alternative Methods Now and Future

- Recombinant Factor C Assay
  - Recombinant form of the horseshoe crab's Factor C enzyme that is activated by endotoxin
  - Developed by National University of Singapore
  - Commercialized and is comparable to LAL
- Monocyte Activation Test – In Vitro Pyrogen Test
  - Test for pyrogens – including endotoxin
- Google "endotoxin detection" you will find links to other assays that detect endotoxin but do not require horseshoe crab blood
- Universities are developing novel methods as well

TAL/LAL End-Users – Role in Conservation

- Supply Chain
  - Who are your critical suppliers?
  - Where/how do they source their materials?
  - What are their quality standards?
  - What are the risks associated with the source?
- Global Supply Chain Initiatives
  - International Chamber of Commerce (ICC) issued a guidance on supply chain responsibility in 2007
  - Companies should do business with vendors who comply with applicable laws and regulations
  - Includes addressing social and environmental issues

Supply Chain Initiatives



- "Supply chain responsibility is a voluntary commitment by companies to take into account social and environmental considerations when managing their relationships with suppliers."
- As example: use a supplier that complies with fair labor laws
- Supply chain initiatives for TAL/LAL end-users should include consideration of the animal source of the TAL/LAL

TAL/LAL End-Users – Role in Conservation

- In evaluating a TAL/LAL supplier, choose one that
  - Uses best practices for harvesting and husbandry of horseshoe crabs
  - And/or offers a non-animal, sustainable alternative
- Validate and implement an alternative method to reduce internal need for TAL/LAL which
  - Can impact the horseshoe crab population
  - Help with risk management of a critical quality control test

Other Consumers – Role in Conservation

- Educate about the horseshoe crab
  - Local level – just flip them
  - Authorities – need for regulation
- Support conservation efforts
  - Help with local beach cleaning and other habitat-friendly efforts
  - Help with survey – crab counting on beach
  - Donate to local conservation groups
  - Help start a conservation group

Is this Beach in Our Future?

We are the TAL and LAL Consumers

Together we can conserve and protect the horseshoe crabs.

Lonza

Thank You