



# INDUSTRY BRIEFS

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THE U.S. MARINE SHRIMP FARMING PROGRAM

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The U.S. Marine Shrimp Farming Program is a congressional initiative administered by the USDA/CSREES. It is an integral part of their aquaculture development effort executed by the US Marine Shrimp Farming Consortium.

## ***Farmers encouraged to complete enclosed OTC survey for FDA's EA***

***By Paula Bender,  
Industry Briefs Editor***

**Although it is geared toward U.S. shrimp farmers**, it should be of interest to many of our subscribers that we are encouraging our farmer membership to participate in the enclosed survey regarding the potential approval of Oxytetracycline (OTC) by the Federal Drug Administration for shrimp culture, regardless of their intention to use it at their facilities.

Completion of the survey, and its subsequent approval, gives all of our farmers another option when it comes to raising shrimp. The questionnaire, created by Investigational New Animal Drug Monitor Rodney Williams of the University of Arizona, is part of the required package of data needed by the FDA for its Environmental Assessment (EA) leading to the possible approval of OTC for shrimp culture.

Initially, the use of OTC was planned for the reduction of mortality associated with Necrotizing hepatopancreatitis (NHP) and vibriosis, which is more wide spread.

For this reason, Williams is gathering information from every farm possible to provide an EA with a scope to include farms that might possibly need to use OTC for vibriosis in the future. Some of the questions may

seem somewhat out in left field, but that data is important to developing the model



***Approval of OTC gives U.S. shrimp farmers one more tool in their arsenal to raise vibrant and healthy animals.***

needed by the FDA to assess the EA.

"We need to gather as much information as possible on all of the factors that might reduce the potential environmental effect of the use of OTC and include them in the model," Williams said. "As such there are questions on particulate loads in ponds, volumes of ponds (for dilution data), pond construction, pond management, and the use of various types of clay."

All of these components are directly involved in estimating the potential OTC quantities that could reach the environment.

"I very much appreciate the time and effort that will be necessary to fully answer this questionnaire, but the information will be invaluable in formulating an EA that the FDA will accept," Williams said.

The survey can be found on pages 4-6.

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The U.S. Marine Shrimp Farming Program is a congressional initiative administered by the USDA/CREES and is an integral part of its agricultural development effort executed by members of the U.S. Marine Shrimp farming Consortium:

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University of Southern Mississippi  
Ocean Springs, MS
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# Farmers' survey is key to FDA approval of OTC

**It's been almost 30 years**, and we still keep plugging away. The approval process for OTC has been very protracted and expensive, taking the good energies of many individuals and organizations. Notably, the

Texas Shrimp Farmers Association has been funding Rod Williams as INAD monitor. Rod has done a tremendous job at keeping the issue up front in the minds of U.S. Food and Drug Administration decision makers and our farming community, with much personal dedication.

The TSFA and USMSFP recently sponsored a trip for Rod to attend the Microbial Food Safety Team meeting in Washington, D.C., where he met with key officials and players while gleaning valuable tidbits to help move the process closer to fruition. The USMSFP also has contributed in conducting efficacy, residue, and Target Animal Safety trials.

We feel we are at the five-yard line now. But it is up to you, the individual farm and farmer, to determine which goal post we are facing. Physical and operational information about your farm is needed for Rod to construct an Environmental Assessment, the next step in the process. This is so important and we are so close, that we have dedicated this entire issue of *Industry Briefs* to encourage farmer participation.

We offer you two options: just fill out the enclosed, pre-paid mailer survey form and pop it in the mail; or visit our website at [www.usmsfp.org](http://www.usmsfp.org), and fill out the information on-line. We also encourage our aquaculture extension agent friends and colleagues to take the survey directly to farmers and fill out the survey together. We understand the effort involved, but without the information, Rod and the rest of us can go no further with the approval process.

Continuation of the INAD is an option as long as the FDA continues to renew it annually as required. That has worked for the past 20 years. But approval requires we maintain the momentum through the EA.

The USMSFP, through Dr. Addison Lawrence, Bill Bray, and the team at TAES, in concert with Rod Williams, are designing another, and hopefully, final Target Animal Safety study that will undergo review by the FDA. Once the design of the study is approved, a decision needs to be made to implement the study. Without the EA, it would be difficult to justify further studies.

Help us help you, the U.S. farmer. Complete the enclosed mailer, go on-line, or get with your extension agent and get the information to us. Your input is key to continuation of the OTC approval process. We appreciate how busy farming is and want to acknowledge that your participation is valuable to us.

# Meticulous care has gone into the study of OTC for shrimp farming

By Donald Lightner, Ph.D.  
University of Arizona  
Department of Veterinary Sciences

**Oxytetracycline, OTC, or Terramycin** as it is known by its commercial name, is very likely the most common antibacterial compound or antibiotic used in food animal production worldwide, and is also the most common antibiotic used by the shrimp culture industries of the world to manage bacterial disease.

OTC has a long history of safe use in food animals. In the United States it has been approved for use in the major food animal species, specifically in cattle, swine and poultry, since the U.S. Federal Drug Administration began to regulate pharmaceuticals for veterinary use. In the so-called "minor species," the use of OTC gained FDA approval in salmonids, catfish and clawed (*Homarus*) lobsters 20 years ago.

In shrimp farming, OTC is used to treat diseases with a bacterial etiology. Most of the diseases for which OTC is efficacious are caused by Gram-negative bacteria that belong to the genus *Vibrio*. Among the most often reported species in this large and mostly marine genus as causing diseases losses globally have been *Vibrio parahaemolyticus*, *V. harveyi*, *V. vulnificus*, *V. penaeicida*, and *V. alginolyticus*.

In many shrimp farms located in arid or semiarid regions of the Americas another serious bacterial disease, necrotizing hepatopancreatitis (NHP for the disease and NHP-B for the agent), occurs usually during the dry hot season, resulting in very high mortality rates if left untreated. OTC has been shown to be efficacious in the management of NHP.

OTC has uses in treating bacterial disease in most of the life history stages of farmed shrimp. In some applications OTC is added to larval-rearing tank water in shrimp hatcheries. However, relatively high dose rates are required for this use since unprotected OTC, when dissolved in sea water, rapidly loses potency as it combines with calcium and becomes biologically unavailable. Hence, the principal use for OTC in shrimp farming is to treat vibrio and NHP-B infections in juvenile stages. Toward that end, the antibiotic is incorporated in the feed at levels that ensure shrimp receive an amount of the drug each day exceeding

the minimum level needed to inhibit the growth of the target bacterial organism, but not so high as to cause adverse effects such as palatability problems, rejection of the medicated feed, or outright toxicity.



**OTC is proven effective for managing necrotizing hepatopancreatitis, or NHP.**

Steps outlined by the FDA for the eventual approval of OTC in U.S. shrimp farms include studies that demonstrate the efficacy of the compound that target the bacterial pathogen(s); the safety of the compound to the shrimp being treated; safety to humans handling the product or consuming as food shrimp that have been treated; and a determination of the fate of the compound in the culture environment.

A variety of studies have been run by Consortium member institutions and other research groups in the United States over the past 30 years to address this. With each study completed we may be one step closer to FDA approval of OTC for use in treating certain bacterial diseases in shrimp.

In the meantime, it is important to remember that shrimp are considered a "minor species" by the FDA and, as such, the approval of OTC falls within FDA's Minor Species Regulations. In the United States, these regulations authorize that the FDA may permit the experimental use of compounds under an INAD (Investigation New Animal Drug) authorization.

The shrimp OTC INADs were amended some years ago to include permission to market treated shrimp after a defined withdrawal period. The OTC INAD is reviewed by the FDA and it has been renewed annually for nearly 20 years. In closing, it is also important to remember that so long as OTC use in shrimp remains unapproved by the FDA, the only way to legally use OTC in U.S. shrimp farms is through the INAD process.

## Farm information:

1. Name of farm: \_\_\_\_\_
2. Farm address: \_\_\_\_\_
3. Owners: \_\_\_\_\_
4. Facility description:  
A. Raceway \_\_\_\_\_ B. Pond \_\_\_\_\_ C. Intensive \_\_\_\_\_  
D. Other (please specify) \_\_\_\_\_

## Pond characteristics:

5. Source of water: \_\_\_\_\_
6. Pond construction: \_\_\_\_\_
7. If clay, amount: \_\_\_\_\_
8. If clay, type: \_\_\_\_\_
9. Pond seepage rate: \_\_\_\_\_

## Farm operations:

10. Shrimp species cultivated: \_\_\_\_\_
11. Typical measurements for normal stocking density per square meter: \_\_\_\_\_
12. Typical average stocking weight of shrimp: \_\_\_\_\_
13. Typical salinity range through growout: \_\_\_\_\_
14. Typical water temperature through growout: \_\_\_\_\_
15. Typical pH range through growout: \_\_\_\_\_
16. Typical secchi disk readings through growout: \_\_\_\_\_

## Pond activity:

17. Length of pond growout cycle: \_\_\_\_\_
18. Are ponds used for other crops? (specify) \_\_\_\_\_
19. Which treatment is applied during dryout period?  
A. Tilling to oxidize the organic load  
B. Treatment with an additive  
C. Removal of the organic load  
D. Other: \_\_\_\_\_
20. If any, what pond particulates and what species of single-cell algae exist in the pond during growout: \_\_\_\_\_

## Feed management:

21. Typical feeding rates for the following animal weight ranges through harvest:  
1-5g \_\_\_\_\_ 6-10g \_\_\_\_\_ 11-15g \_\_\_\_\_ 16-20g \_\_\_\_\_ 21g+ \_\_\_\_\_
22. How is the consumption of feed determined?  
A. Feed tray \_\_\_\_\_ B. Feeding Chart \_\_\_\_\_ C. Other (please state) \_\_\_\_\_
23. Where does uneaten food accumulate in the pond? \_\_\_\_\_

## Water management:

24. Is seawater exchanged during growout with additional seawater? \_\_\_\_\_
25. In what quantities is seawater exchanged and how often during growout? \_\_\_\_\_

**Water management (cont.):**

26. Is seawater exchanged for any of the following reasons?  
A. Blue-green algae bloom \_\_\_\_\_ B. Low oxygen levels \_\_\_\_\_  
C. Other (specify)
- 

27. What body of water is the recipient of the discharged water?
- 

**Effluent management:**

28. During discharge:  
A. Effluent tends to stay at point of entry \_\_\_\_\_  
B. Effluent is mixed significantly with water \_\_\_\_\_  
C. Other (specify)
- 

29. If using a settling area, indicate length of settling time prior to discharge:
- 

30. What is the upper allowable level of suspended solids for discharge in your area?
- 

31. How is solid waste or effluent treated, neutralized or disposed?
- 

**Particulate management:**

32. How do you measure particles at your facility?
- 

33. Please give an estimate of the rate of particle settlement at your facility:
- 

34. Please give an estimate of particle load at discharge:
- 

35. How do you measure particulate removal?
- 

**Facility Diagram:**

To the best of your ability, please provide a diagram of your facility on the next page.

**Use this space** to add any comments regarding your circumstances or concerns:

# 6 OTC MAILER FORM

## Facility Diagram:

Please use this space to draw a diagram of your facility.

**Thank you for your assistance with this survey. If you wish to fax your document please call 520-883-4310 (call before faxing so we may enable the fax machine). You may also fold and secure this page over and use the return address and postage provided below.**



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The US Marine Shrimp Farming Program

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Permit No. 1252

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## Following the OTC Timeline...

2010	◆	Final Approval
2009	◆	Master File Complete
2008	◆	Still needed: --Environmental Assessment
2007		--Microbial Food Safety Package
2006	◆	Target Animal Safety Trials?
2005		
2004		
2003	◆	Target Animal Safety Trials
2002		
2001		
2000	◆	Efficacy Trials data package completed
1999	◆	Residual Trials data package completed
1998	◆	Efficacy Trials
1997	◆	Residue Trials
1996	◆	Manufacturing Feed Stability Study completed
1995	◆	Residue Trials
1994	◆	Efficacy Trials Manufacturing Feed Stability Study
1993	◆	Manufacturing Feed Stability Study
1992		
1991	◆	FDA-CVM filing under University of Arizona
1990	◆	Receipt of INAD number
1979	◆	FDA-CVM filing under Pfizer INAD

## OTC: Where do we go from here?

**The bottom line for final approval** of OTC for shrimp farming in the United States depends on continued funding and the cooperation of farmers. A few more years of work are still required for final approval as we begin to put together the submittal package. This package consists of both data generated from experimental trials and written assessments of the potential environmental impacts of use of OTC.

Currently, the USMSFP is designing an additional Target Animal Safety study required by the FDA Center for Veterinary Medicine (CVM). This study should complete all the experimental data needed for FDA to assess approval. Generally, the CVM takes about four to six months to review a study protocol and one to two years to review the results of that study.

The remaining sections in the submittal package to be completed are the Environmental Assessment and the Microbial Food Safety Package. These two sections could be paper submissions consisting of calculations and data from the literature to devise a model or models for the potential use of OTC in various shrimp farming systems in the United States.

Some of the data generated for the EA will also be used in the Microbial Food Safety package. Additionally, data from all the packages except efficacy can be used to support a claim for use with vibriosis.

Thus, the time to approval is dependent on how soon the remaining information is collected, compiled, and reviewed. As a result, it is expected that it could be 2010 before final approval for use of OTC on shrimp farms in the US is granted, but sooner if our work is done earlier.

--Rodney R. Williams, INAD 8609  
University of Arizona  
Environmental Research Laboratory

**Coming in January 2006**  
**The January 2006 Industry Briefs**  
**will cover a variety of subjects:**

- \*\*Super intensive farming methods**
- \*\*Franchising shrimp farms**
- \*\*Growing bait shrimp**
- \*\*The USMSFP's gold standard of SPF shrimp**

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