Oxytetracycline Medicated Feed Clinical Field Trials - INAD 9332

Year 2003 Annual Summary Report on the Use of Oxytetracycline Medicated Feed in Field Efficacy Trials

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Summary

In support of expanding/extending the current approved label claim for oxytetracycline medicated feed (OTF), the efficacy of OTF was evaluated under compassionate Investigational New Animal Drug (INAD) #9332 in 168 disease control/prevention trials during calendar year 2003 (CY03). Trials were conducted 29 fish culture facilities, including three U.S. Fish and Wildlife Service fish hatcheries, fourteen state hatcheries, one tribal hatchery, and eleven private fish culture facilities to control mortality in a variety of fish caused by one of the following diseases: (1) bacterial coldwater disease, (2) systemic columnaris, (3) streptococcus, (4) gram negative bacterial enteritis, (5) aeromonas/pseudomonas, (6) Edwardsiella Tarda, (7) general systemic bacterial infection, (8) Pseudomonad septicemia, (9) systemic flavobacteriosis, (10) vibriosis, and (11) withering syndrom caused by Rickettsia-like prokaryote. Approximately 30.5 million fish/shellfish were treated with OTF during under this INAD during CY03. The current FDA-approved OTF label limits drug use to the control of

specific bacterial diseases of specific fish species at water temperatures not below 48.2^{o} F (9^{o} C). Label guidelines do not permit the use of OTF to control mortality of fish caused by any of the above-described disease indications. To accommodate the needs of aquaculturists, and to collect data critical to an expansion of the existing approved use of OTF, FDA has authorized the use of this compound under INAD #9332 to control mortality in fishes caused by pathogens for which OTF is not currently unapproved. Investigators at aquaculture facilities that used OTF under this INAD during this period administered treatments under the following broad treatment regimen categories: (1) 0.858 - 2.45 g drug/100 lbs fish/d for 10 - 20 days; (2) 2.5 - 3.75 g drug/100 lbs fish/d for 10 - 15 days; (3) 2.0 or 4.0 g drug/100 lbs fish/d for 10 - 20 days; (4) 3.8 - 9.7 g drug/100 lbs fish/d for 6 - 28 days; (5) 10.0 g drug/100 lbs fish/d for 11 - 15 days; and (6) 12.0 - 15.2 g drug/100 lbs fish/d for 11 - 14 days. Overall, results from OTF treatment trials administered under INAD #9332 during the reporting period indicated that approximately 65% of trials appeared efficacious, 11% appeared ineffective, and 24% were characterized as inconclusive.

Introduction

The current label for oxytetracycline medicated feed (OTF) use in aquaculture limits use to the control of furunculosis in salmonids caused by *Aeromonas salmonicida*, and the control of bacterial hemorrhagic septicemia in salmonids and catfish caused by *A. hydrophila* or *Pseudomonas sp*. Oxytetracycline medicated feed has been shown to be highly effective in controlling these diseases, especially when predisposing

environmental stresses are reduced at the time of treatment (Warren 1991). Furthermore, the current FDA approved label for OTF limits dosage to a range of 2.5 - 3.75 grams of active drug per 100 pounds of fish per day for 10 days, and limits use to water temperatures "not below 48.2^{o} F (9^{o} C). " These label restrictions severely limit the overall utility of approved OTF use in aquaculture.

Historically, OTF treatments have been used by fish culturists to control mortality in salmonids caused by bacterial cold water disease (CWD; causative agent *Flavobacterium psychrophilus*) and columnaris (causative agent (*F. columnare*). Fish culturists and fish health professionals have also found that OTF is effective therapy to control mortality in fishes caused by enteric redmouth (causative agent *Yersinia ruckeri*), vibriosis (causative agent various members of the genus *Vibrio*), and other less common bacterial diseases. However, at this time, OTF is not approved for such uses.

Purpose of Report

The purpose of this report is to summarize the results of calendar year 2003 (CY03) OTF field efficacy trials conducted under INAD #9332. Furthermore, it is expected that data from these trials will be used to enhance the existing OTF database that has been established from previous years studies for the purpose of expanding and/or extending the approved label for OTF.

Facilities, Materials, and Treatment Procedures

1. Facilities

Twenty-nine fish culture facilities, including three U.S. Fish and Wildlife Service fish hatcheries, 14 state, one tribal, and 11 private fish culture facilities used OTF to control mortality in a variety of fish caused by a variety of bacterial and other infectious pathogens in 168 separate field trials. Water temperature during treatments at the various testing facilities ranged from 39.2 - 84.2 °F, with a mean treatment temperature of 66.2 °F.

2. Test article used

The OTF used in CY03 efficacy trials was either Terramycin 100 or Terramycin 100D, both of which contained 100 g active oxytetracycline quaternary salt per pound of premix. All Terramycin 100/100D was supplied by Pfizer, Inc., 1107 South 291 Highway, Lee's Summit, MO. Virtually all oxytetracycline medicated feed used in INAD trials was supplied by several commercial fish feed manufacturers.

3. Treatment regimen

As described in the Study Protocol, Investigators were allowed to use OTF either within the current label range of 2.5 - 3.75 g of active drug/100 lbs of fish/d for 10 - 15 days (approximately 35% of trials were conducted using this treatment regimen) or at 10.0 g of active drug/100 lbs of fish/d for 11 - 15 days

(approximately 17% of trials were conducted using this treatment regimen). However, the treatment regimen administered in the remaining 48% of the trials deviated from the protocol. In these trials, fish were fed at rates of either 0.858 - 2.45 g drug/100 lbs fish/d for durations ranging from 10 - 20 days, 2 and 4 g drug/100 lbs fish/d for durations ranging from 10 - 20 days, 3.8 - 9.7 g drug/100 lbs fish/d for durations ranging from 6 - 28 days, or at 12 - 15.2 g drug/100 lbs fish/d for 11 - 14 days.

Fish Species and Fish Diseases Involved in Year 2003 Trials

1. Species of fish treated

Fourteen fish species, including seven salmonids and seven non-salmonids, and one species of shellfish were treated during CY03. Treated fish ranged in length from 0.75 - 14.3 in. Mean length of treated abalone was 3.15 in. Fish species treated included:

Salmonids: (1) rainbow trout *Oncorhynchus mykiss*; (2) steelhead trout *O. mykiss*; (3) coho salmon *O. kisutch*; (4) chinook salmon *O. tshawytscha*; (5) Apache trout *O. apache*; (6) cutthroat trout *O. clarki*; and (7) brown trout *Salmo trutta*.

Non-salmonids: (1) Mozambique tilapia *Tilapia mossambica*; (2) hybrid striped bass *Morone chrysops* x *M. saxatilis;* (3) muskellunge *Esox masquinongy*; (4)

yellow perch *Perca flavescens*; (5) blue catfish *Ictalurus furcatus*; (6) California halibut *Paralichthys californicus*; and (7) white sturgeon *Acipenser transmontanus*.

Shellfish: red abalone *Haliotis rufescens*.

2. Diseases treated

Test fish were treated to control mortality caused by the following diseases during CY03:

1. Coldwater disease (causative agent *Flavobacterium psychrophilus*)
2. Systemic columnaris (causative agent *F. Columnare*)
3. Streptococcus (causative agent *Streptococcal iniae*)
4. Gram negative bacterial enteritis
5. Aeromonas/pseudomonas
6. Edwardsiella Tarda
7. General systemic bacterial infection
8. Pseudomonad septicemia
9. systemic flavobacteriosis
10. vibriosis
11. Rickettsia-like prokaryote (RLP)

Bacterial coldwater disease (26% of trials) and columnaris (38% of trials) were the diseases most frequently treated during CY03. Treatment of the other nine diseases listed above accounted for the remaining 36% of the treatment trials.

Data Collected

1. Pathologist's reports

Approximately 44% of the data sets submitted to AADAP for CY03 treatment trials included pathologist's reports. Fish health pathology reports typically include: (1) a description of how the identity of disease agent(s) was verified; (2) disease identification records that confirm the presence of the disease agent; and (3) the name and title of the individual performing the diagnosis. Additionally, pathology reports often provide documentation that there were no secondary infections or infestations caused by unrelated disease agents in a population of test fish. As a result, pathology reports provide essential information if efforts are to expand/extend an existing approved label.

2. Mortality data

As stated in the Study Protocol, mortality data were to be collected five days prior to treatment, during the treatment period, and for at least 20 days post-treatment. Investigators were strongly encouraged to collect mortality data on a daily basis. However, daily collection of post-treatment mortality data was not always

possible due to factors such as fish being moved into other tanks or raceways, and fish being stocked to rivers and other bodies of water.

Discussion of Study Results:

1. General observations on the efficacy of OTF for the control of bacterial diseases in salmonid and non-salmonid fish (Note: Table 1 provides a summary of all efficacious trials; Table 2 provides a summary of all ineffective trials; Table 3 provides a summary of all inconclusive trials; Table 4 provides summary data for all trials; and Tables 5a and 5b provide a summary of all trials conducted during CY03 under INAD #9332; Table 5a is sorted by study number; Table 5b is sorted first by disease treated, second by whether treatments were efficacious or not, and lastly by fish species).

A. Efficacy at 0.858 - 2.45 g/100 lbs fish/d for 10 - 20 days at water temperatures above 48.2° F

Fish were treated with 0.858 - 2.45 g OTF/100 lbs of fish/d for 10 - 20 days in 25 trials (Tables 1 - 3). Trials involved rainbow trout diagnosed with bacteria coldwater disease, tilapia diagnosed with streptococcus, and yellow perch diagnosed with columnaris. OTF treatments appeared efficacious in 15 of 25 (60%) trials, ineffective in one of 25 (4%) trials, and inconclusive in nine of 25 (36%) trials.

B. Efficacy at 2.50 - 3.75 g/100 lbs fish/d for 10 - 15 days at water temperatures above 48.2^{o} F

Fish or shellfish were treated with 2.50 - 3.75 g OTF/100 lbs of fish/d for 10 - 15 days in 59 trials (Tables 1 - 3). Trials involved abalone, Apache trout, blue catfish, brown trout, California halibut, coho salmon, cutthroat trout, hybrid striped bass, muskellunge, rainbow trout, spring chinook salmon, tilapia, white sturgeon, or yellow perch. Fish and shellfish were diagnosed with either CWD, systemic columnaris, streptococcus, RLP, Edwardsiella tarda, general systemic bacterial infection, systemic flavobacteriosis, or vibriosis. OTF treatments appeared efficacious in 50 (85%) of the trials, ineffective in three (5%) of the trials, and six (10%) of the trials were characterized as inconclusive.

C. Efficacy at 2.0 & 4.0 g/100 lbs fish/d for 10 - 20 days at water temperatures above 48.2^{o} F

Fish were treated with 2.0 and 4.0 g OTF/100 lbs of fish/d for 10 - 20 days in five trials (Tables 1 & 2). Trials involved yellow perch diagnosed with columnaris. OTF treatments appeared efficacious in three trials and ineffective in two trials.

D. Efficacy at 3.8 - 9.7 g/100 lbs fish/d for 6 - 28 days at water temperatures above 48.2° F

Fish were treated with 3.8 - 9.7 g OTF/100 lbs of fish/d for 6 - 28 days in 45 trials (Tables 1 - 3). Trials involved coho salmon, hybrid striped bass, rainbow trout, tilapia, or yellow perch diagnosed with CWD, columnaris, gram negative bacterial enteritis, or streptococcus. OTF treatments appeared efficacious in 21 (47%) of the trials, ineffective in nine (20%) of the trials, while 15 (33%) of the trials were characterized as inconclusive.

E. Efficacy at 3.8 - 9.7 g/100 lbs fish/d for 6 - 28 days at water temperatures below 48.2° F

Fish were treated with 3.8 - 9.7 g OTF/100 lbs of fish/d for 6 - 28 days in three trials (Tables 1 & 2). Trials involved coho salmon diagnosed with CWD, and OTF treatments appeared efficacious in two trials and ineffective in one trial.

F. Efficacy at 10.0 g/100 lbs fish/d for 11 - 15 days at water temperatures above 48.2°F

Fish were treated with 10.0 g OTF/100 lbs fish/d for 11 - 15 days in 27 trials (Tables 1 - 3). Trials involved chinook salmon, coho salmon, cutthroat trout, rainbow trout, and steelhead trout diagnosed with CWD, columnaris, aeromonas/pseudomonas, or pseudomonad septicemia. OTF treatments appeared efficacious in 17 (63%) of the trials; ineffective in two (7%) of the trials; while eight (30%) of the trials were characterized as inconclusive.

G. Efficacy at 10.0 g/100 lbs fish/d for 11 - 15 days at water temperatures below 48.2^{o}F

Fish were treated with 10.0 g OTF/100 lbs fish/d for 11 - 15 days in two trials (Table 3). Trials involved chinook salmon diagnosed with CWD, and OTF treatments were characterized as inconclusive in both trials.

H. Efficacy at 12.0 - 15.2 g/100 lbs fish/d for 11 - 14 days at water temperatures above 48.2^{o} F

Fish were treated with 12.0 - 15.2 g OTF/100 lbs of fish/d for 11 - 14 days in two trials (Tables 1 & 2). Trials involved cutthroat trout diagnosed with bacteria coldwater disease and fall chinook salmon diagnosed with aeromonas/pseudomonas. OTF treatments appeared efficacious in one trial and inconclusive in the other trial.

2. Observed Toxicity

No toxicity or adverse effects relating to OTF treatment were reported in 167 of the 168 (99%) trials conducted in CY03. However, the Investigator of one study noted that the fish became constipated after treatment with OTF.

Summary of Study Results

Oxytetracycline medicated feed was used at dosages ranging from 0.858 - 15.2 g active drug/100 lbs fish/d. Treatment durations ranged from 6 - 28 days. Treatment trials involved fourteen different fish species and one species of shellfish (i.e., abalone), and approximately 30.5 million fish/shellfish. Treated fish ranged in length from 0.75 - 14.3 in. Mean length of treated abalone was 3.15 in. Water temperature during treatment ranged from 39.2 - 84.2 °F, with a mean treatment temperature of 66.2 °F. Eight trials involved the use of untreated, healthy-appearing, control fish, and approximately 44% of the trials included pathologist's reports. Overall results showed that approximately 65% of trials appeared efficacious, 11% appeared ineffective, and 24% were characterized as inconclusive. In a majority of the trials (89%), OTF treatments appeared either efficacious or were characterized as inconclusive in controlling mortality in a (1) variety of salmonids, particularly cutthroat and rainbow trout, caused by bacterial coldwater disease, (2) blue catfish, yellow perch, musky, hybrid striped bass, and a variety of salmonids caused by columnaris, (3) white sturgeon caused by general systemic bacterial infection, and (4) tilapia caused by streptococcus (Table 5b). Results of trials indicated that mortality decreased during or following the treatment period, and remained at acceptable levels throughout the post-treatment period. Furthermore, in nearly all trials, Investigators reported no evidence of toxicity or adverse effects related to OTF treatment. However, based on a general lack of untreated control fish, replication, randomization, etc., it is understood that these data will only be considered as supportive or ancillary data. None-the-less, the data

described above should provide useful corroborative data to support a future expanded label claim for OTF for these disease indications. It is anticipated that additional ancillary efficacy data will continue to be collected under INAD #9332. In future trials conducted under INAD #9332, efforts will be directed towards the generation of higher quality data.

References

Warren, J.W. 1991. Diseases of hatchery fish. U.S. Fish and Wildlife Service, Portland, Oregon, 92 p.

Table 1. Summary of CY03 OTF Treatment Results - Efficacious Trials

Hatchery	Number of Trials	Fish Species	Fish Size (inches)	Number of Fish	Disease	Number of Treatment Days	Dose (g/100 lbs)	Temp. (°F)
Nampa SFH	1	Rainbow Trout	2.76	49,000	CWD	10	0.858 - 2.45	59.0
Simaron Fresh Water Fish	8	Tilapia	4.6 - 14.3	198,100	Streptococcus	11 - 15	0.858 - 2.45	73.0 - 82.4
St. Croix Waters Tribal Fishery	6	Yellow Perch	1.5 - 4.2	303,415	Columnaris	10	0.858 - 2.45	71.0
The Abalone Farm, Inc	1	Abalone	3.20	148,548	Withering Syndrome	10	2.50 - 3.75	56.0
Alchesay-Williams Creek NFH	2	Apache Trout	1.3 - 1.6	151,700	CWD	10 - 14	2.50 - 3.75	52.0 - 53.0
Farlington SFH	1	Blue Catfish	7.00	10,000	Columnaris	10	2.50 - 3.75	73.0
Alchesay-Williams Creek NFH	1	Brown Trout	0.85	76,800	Systemic Flavobacteriosis	10	2.50 - 3.75	52.0
Hagerman SFH	1	Coho Salmon	3.11	550,000	CWD	10	2.50 - 3.75	59.0
Grace SFH	1	Cutthroat Trout	1.15	138,237	CWD	10	2.50 - 3.75	52.0
Washoe Park SFH	1	Cutthroat Trout	1.60	137,000	CWD	10	2.50 - 3.75	56.0
Hubbs Seaworld Research Institute	1	California Halibut	6.00	200	Vibriosis	10	2.50 - 3.75	73.0
Farlington SFH	1	Hybrid Striped Bass	2.00	19,200	Columnaris	10	2.50 - 3.75	78.0

Table 1. Summary of CY03 OTF Treatment Results - Efficacious Trials - continued

Hatchery	Number of Trials	Fish Species	Fish Size (inches)	Number of Fish	Disease	Number of Treatment Days	Dose (g/100 lbs)	Temp. (°F)
Hackettstown SFH	1	Muskellunge	3.00	17,000	Columnaris	10	2.50 - 3.75	72.0
Alchesay-Williams Creek NFH	1	Rainbow Trout	0.85	272,884	General Systemic Bacterial Infection	10	2.50 - 3.75	52.0
	1	Rainbow Trout	0.85	57,900	Systemic Flavobacteriosis	10	2.50 - 3.75	52.0
Grace SFH	1	Rainbow Trout	6.10	20,543	CWD	10	2.50 - 3.75	52.0
Hagerman SFH	1	Rainbow Trout	3.70	104,000	CWD	10	2.50 - 3.75	59.0
	1	Rainbow Trout	1.95	384,000	Columnaris	10	2.50 - 3.75	59.0
Nampa SFH	1	Rainbow Trout	4.70	176,908	CWD	10	2.50 - 3.75	59.0
Kooskia NFH	1	Spring Chinook Salmon	2.49	703,561	CWD	10	2.50 - 3.75	50.0
Grassy Acre Fish Farm	2	Tilapia	8.00	86,867	Edwardsiella Tarda	10	2.50 - 3.75	80.0
Simaron Fresh Water Fish Inc.	3	Tilapia	3.4 - 10.7	114,014	Streptococcus	14 - 15	2.50 - 3.75	73.4 - 80.6
Farlington SFH	1	Yellow Perch	1.25	6,100	Columnaris	10	2.50 - 3.75	79.0
St. Croix Waters Tribal Fishery	4	Yellow Perch	3.4 - 9.0	357,202	Columnaris	10	2.50 - 3.75	71.0 - 72.0

Table 1. Summary of CY03 OTF Treatment Results - Efficacious Trials - continued

Hatchery	Number of Trials	Fish Species	Fish Size (inches)	Number of Fish	Disease	Number of Treatment Days	Dose (g/100 lbs)	Temp. (°F)
Stolt Sea Farm California	22	White Sturgeon	7.0 - 12.0	22,400	General Systemic Bacterial Infection	10	2.50 - 3.75	68.0
St. Croix Waters Tribal Fishery	3	Yellow Perch	1.5 - 1.7	129,359	Columnaris	10 - 20	2.0 & 4.0	73.0
Neets Bay Hatchery	1	Coho Salmon	2.10	278,768	CWD	12	3.8 - 9.7	48.0
Solomon Gulch Hatchery	1	Coho Salmon	1.70	1,602,876	CWD	20	3.8 - 9.7	46.4
St. Croix Waters Tribal Fishery	1	Hybrid Striped Bass	2.00	177,948	Columnaris	10	3.8 - 9.7	71.0
Murray Springs Trout SFH	1	Rainbow Trout	1.13	50,000	CWD	28	3.8 - 9.7	52.0
Nampa SFH	1	Rainbow Trout	1.36	115,200	CWD	10	3.8 - 9.7	59.0
Simaron Fresh Water Fish	4	Tilapia	3.3 - 10.0	143,300	Streptococcus	9 - 14	3.8 - 9.7	76.3 - 84.2
St. Croix Waters Tribal Fishery	14	Yellow Perch	1.2 - 8.6	1,029,166	Columnaris	10	3.8 - 9.7	71.0 - 73.0
Crystal Lake Hatchery	1	Chinook Salmon	2.80	1,755,000	CWD	14	10.0	54.9
Dexter Ponds	3	Spring Chinook Salmon	3.80	3,259,834	Columnaris	14	10.0	59.8 - 63.1
Rapid River SFH	1	Chinook Salmon	2.80	2,275,215	Pseudomonad Septicemia	14	10.0	51.6

Table 1. Summary of CY03 OTF Treatment Results - Efficacious Trials - continued

Hatchery	Number of Trials	Fish Species	Fish Size (inches)	Number of Fish	Disease	Number of Treatment Days	Dose (g/100 lbs)	Temp. (°F)
Crystal Lake Hatchery	1	Coho Salmon	2.00	299,055	CWD	14	10.0	52.3
Murray Springs Trout SFH	5	Cutthroat Trout	0.9 - 1.9	439,365	CWD	14	10.0	52.0
Washoe Park Trout SFH	3	Cutthroat Trout	1.0 - 2.6	375,800	CWD	14	10.0	52.0 - 56.0
Hagerman SFH	1	Rainbow Trout	1.30	183,688	CWD	14	10.0	59.0
Coleman NFH	1	Steelhead Trout	2.10	11,650	Columnaris	14	10.0	57.0
Magic Valley Steelhead SFH	1	Steelhead Trout	1.73	100,000	CWD	14	10.0	59.0
Murray Springs Trout SFH	1	Cutthroat Trout	0.86	60,000	CWD	14	12.0 - 15.2	52.0

Table 2. Summary of CY03 OTF Treatment Results - Ineffective Trials

Hatchery	Number of Trials	Fish Species	Fish Size (inches)	Number of Fish	Disease	Number of Treatment Days	Dose (g/100 lbs)	Temp. (°F)
St. Croix Waters Tribal Fishery	1	Yellow Perch	3.00	96,702	Columnaris	10	0.858 - 2.45	73.0
American Falls SFH	1	Rainbow Trout	5.60	88,500	CWD	10	2.50 - 3.75	55.0
Grace SFH	1	Rainbow Trout	7.07	121,116	CWD	10	2.50 - 3.75	52.0
Hagerman SFH	1	Rainbow Trout	3.11	425,586	CWD	10	2.50 - 3.75	59.0
St. Croix Waters Tribal Fishery	2	Yellow Perch	2.3 - 2.6	34,530	Columnaris	20	2 & 4	73.0
Hidden Falls Hatchery	1	Coho Salmon	1.30	1,286,065	CWD	6	3.8 - 9.7	39.2
Giant Springs Trout SFH	1	Rainbow Trout	3.93	68,001	CWD	14	3.8 - 9.7	54.0
St. Croix Waters Tribal Fishery	8	Yellow Perch	2.7 - 3.3	432,159	Columnaris	10	3.8 - 9.7	71 - 73
Hagerman SFH	1	Rainbow Trout	1.25	525,000	Columnaris	14	10.0	59.0
	1	Rainbow Trout	1.26	136,043	CWD	14	10.0	59.0

Table 3. Summary of CY03 OTF Treatment Results - Inconclusive Trials

Hatchery	Number of Trials	Fish Species	Fish Size (inches)	Number of Fish	Disease	Number of treatment days	Dose (g/100 lbs)	Temp. (°F)
Simaron Fresh Water Fish Inc.	1	Tilapia	8.90	15,400	Streptococcus	16	0.858 - 2.45	78.8
St. Croix Waters Tribal Fishery	8	Yellow Perch	1.7 - 3.7	258,296	Columnaris	10	0.858 - 2.45	71.0
The Abalone Farm, Inc.	1	Abalone	3.10	129,000	Withering Syndrome	10	2.50 - 3.75	56.1
Hagerman SFH	3	Rainbow Trout	4.2 - 6.0	582,120	Columnaris	10	2.50 - 3.75	59.0
Nampa SFH	1	Rainbow Trout	4.14	20,873	CWD	10	2.50 - 3.75	59.0
Stolt Sea Farm California	1	White Sturgeon	7.00	700	General Systemic Bacterial Infection	10	2.50 - 3.75	68.0
Solomon Gulch Hatchery	1	Coho Salmon	3.70	1,333,700	CWD	14	3.8 - 9.7	49.1
Kent SeaTech	11	Hybrid Striped Bass	2.00	3,256,224	Gram Negative Bacterial Enteritis	10	3.8 - 9.7	77.0
St. Croix Waters Tribal Fishery	3	Yellow Perch	1.7 - 2.6	387,650	Columnaris	10	3.8 - 9.7	71.0
Rapid River SFH	1	Chinook Salmon	3.40	2,839,665	aeromonas/ pseudomonas	15	10.0	51.8
Whitman Lake Hatchery	2	Chinook Salmon	1.7 - 1.9	647,981	CWD	14	10.0	41.7
Murray Springs Trout SFH	1	Cutthroat Trout	1.75	90,300	CWD	14	10.0	52.0

Table 3. Summary of CY03 OTF Treatment Results - Inconclusive Trials - continued

Hatchery	Number of Trials	Fish Species	Fish Size (inches)	Number of Fish	Disease	Number of treatment days	Dose (g/100 lbs)	Temp. (°F)
Hagerman SFH	4	Rainbow Trout	0.75 - 1.5	361,231	CWD	11 - 14	10.0	59.0
Hagerman SFH	1	Rainbow Trout	1.40	100,750	Columnaris	14	10.0	59.0
Irrigon SFH	1	Steelhead Trout	1.50	299,072	CWD	14	10.0	55.0
Umatilla SFH	1	Fall Chinook Salmon	2.00	558,429	aeromonas/ pseudomonas	11	12.0 - 15.2	53.5

Table 4. Summary Data Regarding Summary of CY03 OTF Treatment Trials

Total Fish Treated:	**30,486,896**
Number of fish treated in efficacious trials	16,391,803
Number of fish treated in ineffective trials	3,213,702
Number of fish treated in inconclusive trials	10,881,391
Total number of trials:	**168**
Efficacious trials	109 (65%)
Ineffective trials	18 (11%)
Inconclusive trials	41 (24%)

Trials that Included Control Fish:

Study Numbers: 9332-03-022; 9332-03-042; 9332-03-060; 9332-03-063; 9332-03-068; 9332-03-079; 9332-03-085 (2); and 9332-03-506

Treatment Regimes Used:

0.858 - 2.45 g/100 lbs fish/day for 10 - 20 days (above 48.2°F)	25 trials
2.50 - 3.75 g/100 lbs fish/day for 10 - 15 days (above 48.2°F)	59 trials
2.0 & 4.0 g/100 lbs fish/day for 10 - 20 days (above 48.2°F)	5 trials
3.8 - 9.7 g/100 lbs fish/day for 6 - 28 days (above 48.2°F)	45 trials
3.8 - 9.7 g/100 lbs fish/day for 6 - 28 days (below 48.2°F)	3 trials
10.0 g/100 lbs fish/day for 11 - 15 days (above 48.2°F)	27 trials
10.0 g/100 lbs fish/day for 11 - 15 days (below 48.2°F)	2 trials
12.0 - 15.2 g/100 lbs fish/day for 11 - 14 days (above 48.2°F)	2 trials

Treatment Water Temperature (°F):

Temperature Range	39.2 - 84.2
Mean Temperature	66.2

Size of Treated Fish (in.):

Size Range	0.75 - 14.3

Species Treated:

Salmonids
rainbow trout *Oncorhynchus mykiss*
steelhead trout *O. mykiss*

coho salmon *O. kisutch*
chinook salmon *O. tshawytscha*
Apache trout *O. apache*
cutthroat trout *O. clarki*
brown trout *Salmo trutta*

Non-salmonids
Mozambique tilapia *Tilapia mossambica*
hybrid striped bass *Morone chrysops* x *M. saxatilis*
muskellunge *Esox masquinongy*
yellow perch *Perca flavescens*
blue catfish *Ictalurus furcatus*
California halibut *Paralichthys californicus*
white sturgeon *Acipenser transmontanus*

Shellfish:
red abalone *Haliotis rufescens*