A CLINICAL FIELD TRIAL TO DETERMINE:

# The Efficacy of Florfenicol-Medicated Feed to Control Mortality of Fingerling Coho Salmon *Oncorhynchus kisutch* Caused by Furunculosis, Causative Agent *Aeromonas salmonicida*.

**Study Number: FLOR-01-EFF-01**

ORIGINAL


**Study Director**

James D. Bowker
U.S. Fish and Wildlife Service
Bozeman Fish Technology Center - National INAD Office
4050 Bridger Canyon Road
Bozeman, MT 59715
Phone: 406-587-9265 ext. 126
FAX: 406-582-0242

**Investigator**

Al Jensen
U.S. Fish and Wildlife Service
Makah National Fish Hatchery
P.O. Box 739
Neah Bay, Washington

Testing Site: Makah National Fish Hatchery
P.O. Box 739
Phone: 360-645-2521
Fax: 360-645-2658


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James D. Bowker D. B 9/28/01

Daniel Carty Daniel Carty 9/28/01

## Abstract

The United States Fish and Wildlife Service's (USFWS) National Investigational New Animal Drug Office (NIO) designed and conducted an efficacy study to generate data needed to obtain U.S. Food and Drug Administration approval for the use of florfenicol-medicated feed to control mortality in hatchery-reared salmonids diagnosed with furunculosis, causative agent *Aeromonas salmonicida*. The study was conducted at the USFWS Makah National Fish Hatchery (NFH; Neah Bay, WA) by staff from the NIO and the Makah NFH following guidelines described in Study Protocol Number FLOR-01-EFF. The objective of the study was to compare mortality between fingerling coho salmon *Oncorhynchus kisutch* fed florfenicol-medicated feed and fingerling coho salmon fed non-medicated feed. Fish used in the study had been diagnosed with furunculosis by identification of *A. salmonicida* cultures grown on Brain Heart Infusion Agar (BHIA) that had been streaked with kidney and spleen tissues from (1) fish sampled 5 d before the start of the study and (2) from fish sampled on the first day of the study. On the first day of the study, fish selected from a reference population held in one raceway were distributed equally among 12 test tanks. A completely randomized design procedure was used to assign a treatment condition of either "treated" or "untreated" to each test tank. Test fish in 6 of the 12 test tanks were fed florfenicol-medicated feed at a target dosage of 10 mg florfenicol/kg of fish/d for 10 consecutive days. Test fish in the other six test tanks were fed non-

medicated feed during the same 10-d period. Following the treatment period, test fish in all 12 test tanks were fed non-medicated feed. Blinding techniques were employed to ensure that study participants involved in day-to-day data collection did not know which test tanks of fish were fed medicated feed and which test tanks of fish were fed non-medicated feed. The study was scheduled to last 25 d and to consist of a 1-d acclimation period, a 10-d treatment period, and a 14-d post-treatment period. However, because of discovery of a low-level infection of a secondary disease agent (presence of the external parasite *Trichodina* sp. on some test fish) on d 7 of the post-treatment period, the study only lasted 18 d (i.e., a 1-d acclimation period, a 10-d treatment period, and a 7-d post-treatment period). Although the presence of this parasite on some fish was not at a pathogenic level at the time it was discovered, it was suspected that if left untreated, the infection might escalate to a high enough level to become pathogenic. Consequently, the study was terminated, somewhat prematurely, on day 7 of the post-treatment period. Mortality that occurred during the treatment and post-treatment periods of the study was the primary response variable. Percent total mortality for each test tank was calculated by dividing the number of dead fish removed from each test tank by the number of live fish hand-counted and transferred to each test tank at the beginning of the study. At the end of the study, mean percent total mortality in the group treated with florfenicol-medicated feed (11.1%) was significantly less ($P < 0.001$) than mean percent total mortality in the group not treated with florfenicol-medicated feed (30.3%). Test fish were maintained under conditions

adequate for rearing healthy salmonids, and mortality observed in the study was attributed to infection of furunculosis. Consequently, results from this study demonstrate that the target treatment regimen of 10 mg florfenicol/kg of fish/d fed on 10 consecutive days is effective in controlling mortality in juvenile coho salmon caused by furunculosis.