

## **Common Carp Pituitary Clinical Field Trials - INAD 8391**

### Year 2001 Annual Summary Report on the Use of Common Carp Pituitary in Field Efficacy Trials

Prepared by:

Bonnie Johnson, Biologist  
U. S. Fish and Wildlife Service  
Bozeman National INAD Office  
Bozeman, Montana

### **Summary**

Spawning aids such as luteinizing hormone-releasing hormone analogue, human chorionic gonadotropin, and common carp pituitary (CCP) are routinely used in fisheries programs to induce gamete maturation in fish to enhance fish propagation programs. The U.S. Food and Drug Administration has authorized the use of CCP under the Compassionate Investigational New Animal Drug (INAD) Exemption #8391 for the purpose of gathering efficacy data to support a new animal drug approval for CCP. Several INAD trials were conducted in calendar year (CY) 2001 to evaluate the efficacy of CCP to induce gamete maturation in a variety of fish species. Thirty-one such trials that involved 2,357 treated fish were conducted at one state hatchery and one private hatchery during this period. Efficacy was determined by whether or not treated fish (1) produced or yielded eggs or milt, or (2) produced or yielded more eggs or milt than untreated fish more. Overall results of trials conducted in CY 2001 showed that

approximately 88% of the trials appeared efficacious, 6% appeared ineffective, and 6% were characterized as inconclusive.

## **Introduction**

The use of hormones to induce spawning in fish is critical to the success of many federal, state, private, and tribal fisheries programs. A wide variety of programs, including several that involve the restoration of threatened/endangered species are dependent upon hormone treatment to complete final gamete maturation and ensure successful spawning.

The time of spawning is by its own nature a stressful period for all fish species. The handling required during the artificial spawning of fish complicates an already delicate situation. In order to maintain the health of both wild and domestic brood fish, it is beneficial to minimize overall fish handling. Successful hormone treatment can reduce handling requirements to a single hormone administration event followed by actual gamete collection, thereby greatly reducing overall fish handling. In many cases, especially with respect to captured wildstock species, final gamete maturation will not occur without hormone treatment.

Final gamete maturation in fish can be induced by the administration of a variety of hormones. Common carp pituitary (CCP) has been shown to induce gamete maturation in a number of fish species, including certain threatened and endangered species. Common carp pituitary, which has been shown to be particularly effective when used in cool and warm water species, has had a significant, positive impact on federal, state, private, and tribal programs nationwide.

## **Purpose**

The primary purpose of this report is to summarize the results of CY 2001 supplemental CCP field efficacy trials. However, it is also expected that these data will be used to enhance the existing CCP database that has been established from previous years trials for the purpose of supporting a new animal drug approval for the use of CCP in aquaculture.

## **Facilities, Materials, and Methods**

### **1. Participating Facilities**

A total of two fish culture facilities used CCP during CY 2001, including one state fish hatchery and one private fish hatchery .

## **2. CCP used in trials**

All CCP used in CY 2001 trials was supplied by Stoller Fisheries, Spirit Lake IA.

## **3. Drug dosages**

As described in the Study Protocol, Investigators were allowed to use CCP at dosages ranging from 4 to 10 mg CCP/kg body weight (bw). The drug dosages used in these trials ranged from 6.6 to 10 mg CCP/kg bw and were used to induce gamete maturation in females only (no males were treated). CCP was administered as either a single intraperitoneal (IP) injection, or as a series of two IP injections.

## **Fish Species and Gender Treated**

### **1. Species of fish treated**

The following two fish species were treated with CCP during CY 2001.

channel catfish *Ictalurus punctatus*

muskellunge *Esox masquinongy*.

## **2. Gender of fish treated**

A total of 2,357 females were injected with CCP during CY 2001. No males were treated. Typically, females are treated with spawning hormones to shorten the egg maturation period or synchronize ovulation.

## **Data Collected**

### **1. Pathologists Reports**

Fish health pathology reports provide essential information with respect to disease confirmation and general fish health. However, no pathology reports were submitted during CY 2001 trials.

### **2. Primary response variables**

The primary response variables for evaluating the effect of CCP were the relative number of fish that ovulated or reach active spermiation. With respect to the treatment of females, in some cases, percent hatch and percent eyed eggs was also determined.

### **3. Spawning interval**

The period of time between the final CCP treatment and when treated fish were evaluated for gamete maturation was documented.

## **Discussion of Study Results**

### **1. Summary results on the efficacy of CCP to induce gamete maturation**

(Note: Summary of CY 2001 CCP efficacy results are listed in Table 1; summary data regarding Cy 2001 CCP efficacy trials are listed in Table 2; and a summary of all state and private individual CCP trials conducted are listed in Table 3.)

#### **A. Efficacy at 6.6 mg/kg bw**

Six trials were conducted in which female muskellunge were injected with CCP at a dosage of 6.6 mg/kg bw (Table 1). Two trials involved use of non-treated control groups. Percent ovulation ranged between 0 - 80%. None of the control fish ovulated. Four treatments appeared efficacious. Two trials appeared ineffective.

#### **B. Efficacy at 10.0 mg/kg bw**

Twenty-five trials were conducted in which female channel catfish were treated with CCP at a dosage of 10.0 mg/kg bw (Table 1). Percent ovulation in groups of test fish ranged from 30 - 94%.

Treatment appeared efficacious in 23 trials. Treatment in two trials was characterized as inconclusive.

## **2. Observed Toxicity**

No toxicity or adverse effects relating to CCP treatment were reported.

### **Summary of Study Results**

The efficacy of CCP was tested in 31 trials involving female muskellunge and channel catfish treated at dosages ranging from 6.6 to 10.0 mg/kg bw. Treatment was administered as either a single IP injection, or as a series of two IP injections. Of the 31 trials conducted, two utilized non-treated control groups. A total of 2,357 adult fish were treated. Water temperature during treatment ranged from 52 - 84°F. CCP treatment appeared to be efficacious in 88% of the trials, ineffective in 6% of the trials, and inconclusive in 6% of the trials. Investigators reported no evidence of toxicity or adverse effects related to CCP treatment. It is understood that these data can only be considered as ancillary data. None-the-less, the ancillary data described above should provide useful corroborative data to support a new animal drug approval for CCP. It is anticipated that additional ancillary efficacy data will continue to be collected under INAD #8391. In future trials conducted under INAD #8391, efforts will be directed towards the continued generation of high quality data.

Table 1. Summary of CY 2001 CCP Efficacy Results							Females				Males			
							Treated		Control		Treated		Control	
Apparent Efficacy	Number of Trials	Facility	Species	Treatment Method	Dose (mg/kg)	Spawning Interval (hr)	Number Treated	% Ovulate	Number Controls	% Ovulate	Number Treated	% Spermiate	Number Controls	% Spermiate
Efficacious	23	Harvest Select Farms	Channel Catfish	Injection	10	26	2,139	56 - 94	0	na	0	na	0	na
Inconclusive	2	Harvest Select Farms	Channel Catfish	Injection	10	26	200	30 - 47	0	na	0	na	0	na
Efficacious	4	Hackettstown SFH	Musky	Injection	6.6	4 days	12	33 - 100	1	0	0	na	0	na
Ineffective	2	Hackettstown SFH	Musky	Injection	6.6	Every 2 days for up to 8 days	6	0	5	0	0	na	0	na

**Table 2. Summary Data Regarding CY 2001 CCP Efficacy Trials**

---

<b>Total Number of Trials Conducted:</b>	31
<b><u>Number of Efficacious Trials:</u></b>	27
<b><u>Number of Ineffective Trials:</u></b>	2
<b><u>Number of Inconclusive Trials:</u></b>	2
<b>Total Number of Fish Treated:</b>	2,357
<b>Treatment Regimes Used:</b>	
<b><u>6.6 mg/kg body weight (one injection)</u></b>	6 trials
<b><u>10.0 mg/kg body weight (two injections)</u></b>	25 trials
<b>Treatment Water Temperature (°C):</b>	52.0 - 84.0
<b>Size of Treated Fish:</b>	Adult
<b>Species Treated:</b>	channel catfish <i>Ictalurus punctatus</i> muskellunge <i>Esox masquinongy</i>

---



