



**In the U.S. Aquaculture Drug-Approval World,  
*Oncorhynchus mykiss* by Any Other Name is Still *Oncorhynchus mykiss***

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*Oncorhynchus mykiss* and its subspecies are native only to western North America (Behnke 1992). However, as a result of myriad introductions, *O. mykiss* now has a worldwide distribution and is, perhaps, the most well known trout in the world.

In U.S. aquaculture, the most commonly reared forms of *O. mykiss* are rainbow trout and steelhead. Both forms are typically reared in freshwater hatcheries for use in fishery management or native fish restoration programs. In addition, rainbow trout are also reared for direct shipment to commercial markets.

Until 2007, the U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine categorized freshwater-reared rainbow trout, steelhead, and other *O. mykiss* subspecies as "different fish species" with respect to the use of aquaculture drugs. Consequently, there was concern that researchers would be required to conduct drug efficacy studies on rainbow trout, steelhead, and one or more other *O. mykiss* subspecies to obtain a new or expanded aquaculture drug approval for "all freshwater-reared *O. mykiss*."

In 2007, the U.S. Fish and Wildlife Service's (FWS) Aquatic Animal Drug Approval Partnership (AADAP) Program submitted a "white paper" to FDA in which AADAP argued that results of controlled drug efficacy trials conducted on freshwater-reared rainbow trout, steelhead, or for that matter any *O. mykiss* subspecies, should be transferrable to all freshwater-reared *O. mykiss*. Essentially, AADAP argued that - with respect to aquaculture drug approvals - *O. mykiss*, by any other name, is still *O. mykiss*. This bulletin summarizes AADAP's arguments and FDA's response.

### AADAP's Arguments

#### *Taxonomy and Life History*

Rainbow trout and steelhead are the same "fish" (*O. mykiss*), although they exhibit different life history strategies (Behnke 1992; Nelson et al. 2004). Rainbow trout typically complete their life cycle in freshwater, whereas steelhead are typically anadromous. However, common to both life histories is that

spawning, egg incubation, hatching, and early rearing (fry to at least fingerling) occur in freshwater. Although originally these forms of *O. mykiss* were classified as two distinct species based on morphology and behavior, they have since been reclassified as a single species (Behnke 1992; 2002).

#### *Scientific Findings*

Steelhead conservation work has included research on the degree of genetic differentiation between steelhead and rainbow trout. Modern genetic analysis has demonstrated that differentiation between similar life-history forms of two different subspecies within a single river basin is less than the genetic differentiation between the same subspecies occupying different river basins. For example, summer steelhead are genetically more similar to winter steelhead of that system than they are to summer steelhead in other systems (McEwan 2001). This finding indicates (1) the degree of relatedness among *O. mykiss* populations is associated with geographic proximity and not with life history (Olsen et al. 2006) and (2) steelhead and rainbow trout are polyphyletic and the result of parallel evolution rather than members of two distinct lineages (Docker and Heath 2003). Other research has demonstrated that juvenile rainbow trout can adopt a life-history strategy that is different from their parents (McEwan 2001; Good et al. 2005), providing further evidence that the two "fish" are genetically linked.

#### *Culture of *Oncorhynchus mykiss**

Similar techniques are used in the freshwater culture of rainbow trout and steelhead. Generally, both are reared in the same water, under the same culture and environmental conditions, and are fed the same feed (Charlie Smith, FWS – retired, personal communication). It is often difficult, if not impossible, to differentiate between the two based on morphology of pre-release fish, i.e., fry or fingerling (Mark Olson, FWS, personal communication). Steelhead are typically held in the hatchery for no more than 12 months before release to freshwater tributaries, at which time they may or may not begin to smolt. However, the morphological, physiological, and behavioral changes associated with

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smoltification result in minimal changes with respect to fish culture; although smoltification may diminish steelhead feed consumption (Behnke 2002). As a result, steelhead returning to the hatchery to spawn typically do not feed.

#### *2005 Fish Production Database*

In 2005, the AADAP Program assembled a *Fish Production Database* (FPD) documenting fish produced in the U.S. by public sector aquaculture. Based on the FPD, public aquaculture reared 118 million *O. mykiss* in 2005. Of the 87 million rainbow trout produced, only 70,000 were classified as broodstock. Of the 31 million steelhead produced, only 9,000 were classified as broodstock. Although all life-stages of *O. mykiss* are reared or held at hatcheries and are potentially subject to treatment with one or more therapeutic drugs, a relatively inconsequential number of steelhead are held as broodstock. Adult steelhead returning to a hatchery are not held for long before being spawned. Early life-stage steelhead reared at a hatchery have yet to fully undergo the changes that distinguish them morphologically or physiologically from rainbow trout. These data support the premise that drug treatment applied in a hatchery will nearly always be administered to pre-hatchery release *O. mykiss*.

#### **Summation of AADAP's Argument**

Rainbow trout and steelhead are the same species, although they have different life history patterns. Genetic analysis has confirmed that rainbow trout and steelhead belong to the same species. The culture techniques used to rear both fish are virtually identical, and morphological or physiological differences are indiscernible while fish are held in the hatchery. Hence, we further conclude that if an aquaculture drug has been demonstrated to be effective in steelhead, it should be equally effective in other subspecies of *O. mykiss* reared under similar conditions, and vice-versa.

#### **FDA/CVM's Response**

The FDA agreed that AADAP's arguments support the assertion that effectiveness data accepted for freshwater-reared rainbow trout or steelhead have substantive inferential value for all *O. mykiss* subspecies ([http://www.fws.gov/fisheries/aadap/CVM%20response%20letters/2007\\_07\\_25\\_P-0106\\_O%20mykiss%20response%20letter.pdf](http://www.fws.gov/fisheries/aadap/CVM%20response%20letters/2007_07_25_P-0106_O%20mykiss%20response%20letter.pdf)). Thus, in the future, it should be easier for researchers to obtain FDA approval for new or expanded aquaculture drug claims for "all freshwater-reared *O. mykiss*."

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