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AFS Policy Statement on Fish Sedatives Kick-starts Dialogue with Regulators; Immediate-release Sedative Becomes Available for Field Use Under National INAD Program

J. Bowker and J. Trushenski

Fisheries professionals have long needed legal access to a drug that would allow fish to be sedated and immediately returned to the environment, but there are currently no legal options for such uses. This dilemma prompted the American Fisheries Society to adopt a new policy statement on the need for an immediate-release anesthetic/sedative for use in the fisheries disciplines, calling attention to the need for better options for sedating fish during handling. As part of a strategic plan to more effectively utilize policies statements to better inform others of AFS's position on specific topics, Dr. Gus Rassam (AFS Executive Director) provided the approved policy to Drs. Bernadette Dunham (Director, U.S. Food and Drug Administration Center for Veterinary Medicine [FDA CVM]) and Steven Vaughn (Director, FDA CVM Office of New Animal Drug Evaluation [ONADE]). In addition, a meeting was requested of the AFS and FDA CVM 'top brass' to discuss the content of the policy statement in greater detail. On April 25, 2012, leading representatives of AFS, FDA CVM, and the fish drug research and development community met for an unprecedented meeting at the FDA CVM offices in Rockville, Maryland. The leaders of virtually every FDA CVM office and team involved in fish drug approvals, including Drs. Dunham and Vaughn, came to the table for a frank discussion of fish drug issues, including:

Why are compounds considered "Generally Recognized As Safe" in human food considered risky if used to sedate fish that people will consume?

If quality control and manufacturing standards are tailored to the intended use in some areas of food and drug production, why are human drug manufacturing standards applied to fish drugs?

Given these purity, safety, and efficacy concerns regarding fish drugs, why are so many illegal products allowed to be directly marketed to fishermen and fisheries professionals?

In a future issue of Fisheries, you'll see FDA CVM's response to these and other "Frequently Asked Questions" regarding fish sedatives and other drugs—some of the answers may surprise you. But there is one exciting announcement that can not wait:

Authorization has been granted for the use of AQUI-S@20E as an immediate-release sedative for field use under USFWS INAD!

The FDA recently granted amended authorization for the use of AQUI-S@20E (10% eugenol), a sedative drug, to allow for the immediate release of freshwater finfish sedated as part of field-based fisheries management activities. The amended authorization allows use of this product as an immediate-release fish sedative for the above-described use when used under the U.S. Fish and Wildlife Service's Aquatic Animal Drug Approval Partnership (USFWS-AADAP) Investigational New Animal Drug (INAD) 11-741. Although eugenol is also the active ingredient in clove oil (clove oil is 85-95% eugenol), AQUI-S@20E is the only product which can be used under the amended INAD authorization; it is not legal to use clove oil as a fish sedative.

Access to an immediate-release fish sedative represents a significant landmark for the Association of Fish and Wildlife Agencies (AFWA), its Fisheries and Water Resources Policy Committee's Drug Approval Working Group (DAWG), USFWS-AADAP, U.S. Geological Survey Upper Midwest Environmental Sciences Center (UMESC), and the drug sponsor AQUI-S New Zealand, Ltd.

"The collaborative efforts of federal natural resource and science agencies, state fish and wildlife agencies, and drug sponsors are critical to increasing the number of approved drugs available to protect fish health and thereby enhance our nation's fishery resources," said Virgil Moore, Idaho Department of Fish and Game Director and chair of AFWA's Fisheries and Water Resources Policy Committee. "The immediate-release authorization for AQUI-S@ 20E represents one step in the entire approval process for



Brown trout being measured for total length following sedation to handleable with AQUI-S20E (25 mg eugenol/L water). Fish were being sedated as part of a collaborative effort to support FDA approval of AQUI-S20E as a fish sedative. Photo credit: USFWS.

the sedative, but it is an extremely positive step forward,” said Steve Sharon, Fish Culture Supervisor from the Wyoming Game and Fish Department and DAWG chair. “Not only will it have an immediate, positive impact on field-based fisheries management activities throughout the country, but it is a clear indication that we are indeed on the track to full approval.”

Fisheries professionals may access AQUI-S® 20E by signing up to participate in USFWS-AADAP INAD 11-741. For more information, please see the full AFWA press release (http://www.fishwildlife.org/index.php?section=afwa_press_releases&prid=180), or visit the USFWS-AADAP website (<http://www.fws.gov/fisheries/aadap/AQUIS-E.HTM>).

The U.S. Fish and Wildlife Service Aquatic Animal Drug Approval Partnership (USFWS-AADAP) Program is a nationwide, partnership-based program located in Bozeman, Montana. The mission of the USFWS-AADAP Program is “Working with our partners to conserve, protect, and enhance the Nation’s fishery resources by coordinating activities to obtain FDA approval for drugs, chemicals, and therapeutants needed in aquaculture and fisheries management programs.” Aquaculture in the United States has struggled because of a shortage of FDA-approved drugs for use in aquatic species. This situation jeopardizes the health and fitness of aquatic species held in captivity, many of which are key to conservation and restoration efforts of the USFWS and its many partners. To address this problem, the USFWS-AADAP Program actively pursues safe and effective new aquatic animal drug approvals and administers the National INAD Program. In fulfilling its mission, the USFWS-AADAP Program supports hundreds of federal, state, tribal, and private fish culture and management operations. For more information about the USFWS-AADAP Program and its many services, visit <http://www.fws.gov/fisheries/aadap/home.htm>.

AFS POLICY STATEMENT

Availability of safe and effective fish sedatives or anesthetics is crucial to fisheries research, management, and culture activities. Unlike most terrestrial vertebrates which may be handled without causing mechanical damage, fishes are particularly vulnerable to external and internal injury during physical restraint. Fish that are handled without proper sedation may also be negatively affected by the physiological consequences of the generalized stress response.—AFS Policy Statement #34f: The Need for an Immediate-Release Anesthetic/Sedative for Use in the Fisheries Disciplines: http://fisheries.org/docs/policy_statements/policy_34f.pdf

North American Fish Extinctions May Double by 2050

From 1900 to 2010, freshwater fish species in North America went extinct at a rate 877 times faster than the rate found in the fossil record, and estimates indicate the rate may double between now and 2050. This new information comes from a U.S. Geological Survey (USGS) study published in the September issue of the journal *BioScience*.

In the fossil record, one freshwater fish species goes extinct every 3 million years, but North America lost 39 species and 18 subspecies between 1898 and 2006. Based on current trends in threatened and endangered fish species, researchers estimate that an additional 53–86 species of freshwater fish may be extinct by the year 2050. Since the first assessment of extinct North American freshwater fishes in 1989, the number of extinct fishes increased by 25%.

“This study illustrates the value of placing current events into the context of deep geologic time, as rocks preserve an unbiased record of natural rates of processes before human activities began to alter the landscape, the atmosphere, the rivers, and oceans,” said USGS Director Marcia McNutt. “Freshwater fish are a good choice for analysis as their bones make clear fossil impressions, and their lake and river environments produce excellent stratigraphic sequences.”

The study’s author, Noel Burkhead, used an established method to compare the rate of extinction found in the fossil record with modern rates. “Estimates of freshwater fish extinctions during the twentieth century are conservative, because it can take 20–50 years to confirm extinction,” said Burkhead, a research fish biologist for the USGS.

Extinction is a natural process, Burkhead explained, so examining its rate over a long geological timescale provides biologists with a benchmark for comparing current extinctions to background rate. The accelerated pace of extinction observed since the beginning of the 20th century suggests human causes.



Diplomystus dentatus fossil with *Knightia* in its mouth. Photo Credit: Arvid Aase of Fossil Country Museum specimen.

In North America, assessments of extinctions are conducted by the American Fisheries Society's Endangered Species Committee, using categories to factor in a lag time since the last observation of the species. The study used the categories "extinct" (species not seen for 50 years or more), "possibly extinct" (not seen for 20 years or more), and "extinct in nature." All of these categories require that searches for the missing fishes must have been made by knowledgeable biologists.

"It is extremely rare that the death of the last individual is documented by biologists," said Burkhead, "although it can happen when a fish only is found in a specific spring or caldera, and it dries up. That's what happened with five species of desert pupfishes and the Alberca silverside—the last known fish to go extinct in North America."

The Alberca silverside was found only in the Alberca Caldera, Guanajuato, Mexico; it went extinct when the caldera temporarily dried up in August 2006.

Surprisingly, Burkhead reported that 90–96% of fish extinctions in the fossil record were not linked to the five well-known mass extinctions. Natural causes of fish extinction are linked to transitions in landforms and continental watercourses over time, but many 20th-century extinctions were caused by dams, channelization of rivers, water pollution, and other human-induced factors.

The background rate of extinction is based on the fossil record, which includes information on when ancient fishes lived and how long species survived in the geological past. Burkhead used data on fish extinctions from well-known paleontologist Steven M. Stanley at the University of Hawaii.

"Another cause of extinction can be a change in a fish's food chain, which is what may have happened to the harelip sucker, a really cool fish that used to live in seven states throughout the Ohio River basin," said Burkhead.

The hairlip sucker was a snail-eating specialist with cleft lips that used to pluck snails off river bottoms and manipulate the snail in its mouth in order to suck out the snail's soft parts, perhaps making little popping sounds. Sadly, snails are highly sensitive to excessive sedimentation and in the late nineteenth century, large amounts of topsoil were washing into rivers along with sewage and industrial effluents from cities. This likely caused snails to decline, which may have been what drove the fish to extinction.

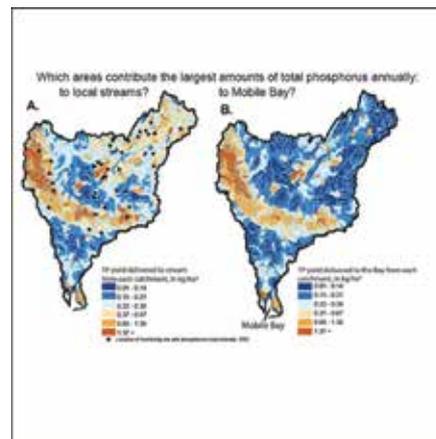
Declines in freshwater fishes are only the "tip of the iceberg" for freshwater ecosystems, with mussels and snails experiencing declines greater than that of freshwater fishes.

AFS POLICY STATEMENT

Recent status assessments conducted by the AFS and its subunits clearly indicate systematic declines in native fish distribution and abundance throughout North America. About one-third of the freshwater fish taxa in North America are endangered, threatened, or of special concern, with membership in each category exhibiting substantial increases during the last decade. At least 106 Pacific coast stocks of anadromous salmon and trout are extinct, and 214 more are at risk of extinction or of special concern status. These trends indicate that the current high rates of freshwater fish extinction will persist into the 21st century.—AFS Policy Statement #27: Conservation of Imperiled Species and Reauthorization of the Endangered Species Act of 1973: http://fisheries.org/docs/policy_statements/policy_27f.pdf

New Maps Show Nutrient Delivery to Gulf of Mexico

For those in need of information on estimates of yields and information on sources of nutrients transported to 21 estuaries, bays, and sounds in the Gulf of Mexico, the U.S. Geological Survey (USGS) Spatially Referenced Regression on Watershed Attributes (SPARROW) system has maps posted here: <http://water.usgs.gov/nawqa/sparrow/mrb/gov>. These estimates are based on the SPARROW models developed for the southeastern and south-central United States and integrate federal, state, and local agency monitoring data at over 700 stations. These maps show where estimated nutrient yields are elevated locally and which areas have the highest yields to downstream estuaries, bays, and sounds in the Gulf of Mexico. SPARROW's online, interactive decision support system—<http://cida.usgs.gov/sparrow>—provides easy access to these regional models, describing how rivers receive and transport nutrients from natural and human sources



Map *kg/ha, kilograms per hectare. Total nitrogen or phosphorus yields. Photo Credit: <http://water.usgs.gov>.

to sensitive waters throughout the Gulf of Mexico. Users can evaluate source reduction scenarios that target one or more nutrient sources to evaluate changes in the amount of nutrients transported downstream.

AFS POLICY STATEMENT

A critical question is: what quantitative criteria related to population decline best reflect risk of extinction for marine fishes?—AFS Policy Statement #31af: Protection of Marine Fish Stocks at Risk of Extinction: http://www.fisheries.org/docs/policy_statements/policy_31af.pdf

New Coin and AFS Books!

Attention all you over-30-pound-chinook fans (yeah, you Tyeer lovers)—the Royal Canadian Mint has devoted a pure \$3 silver coin, plated in two tones of gold, to the likes of your favorite fish. Why? Because this fish been an essential food source for the folks living along the Northwest Coast for centuries; hence, it was time to honor these anadromous swimmers. Journalist Dennis Rainey recently broke the news of the newly minted coin in an article for World Coin News, adding some interesting facts about the Tyeer, including:

The record weight for a sport-caught chinook is 97.25 pounds (44 kg) from the Kenai River in Alaska in 1985. The record commercial chinook is 126 pounds (57 kg) taken in British Columbia, Canada, in the late 1970s.

and

The Tyeer Fishing Club of British Columbia was formed in 1924 by three men discussing tuna sport fishing in a hotel who agreed that fishing for large chinooks was fully as exciting as catching a large tuna. They formed the Tyeer Fishing Club in 1925 to create interest in Canada's chinook salmon, emphasizing sportsmanship and encouraging young people into the business of guiding and sportsmanship.

At the end of the article, he went on to give the American Fisheries Society some deserved recognition, “The following publication is highly recommended: Quinn, Thomas P., *The Behavior and Ecology of Pacific Salmon and Trout*. 2005. American Fisheries Society and The University of Washington Press, 378 pp.”



The newly minted \$3 Tyeer coin.



Dr. Richard "Rick" Shaw.
Photo Credit: Louisiana State University.

Dr. Richard "Rick" Shaw, Appointed

Dr. Richard "Rick" Shaw (American Fisheries Society '75), the Associate Dean of the School of the Coast and Environment and a professor in the Department of Oceanography and Coastal Sciences at Louisiana State University (LSU), was nominated by the state of Louisiana—then appointed—to serve on the Gulf of Mexico Research Initiative (GoMRI) Research Board. The GoMRI Research Board is an independent board that oversees and administers BP's \$500 million research fund that supports investigations for the next 10 years into the impacts of the oil spills and dispersants used to clean them up and the environmental and health complications that arise from such spills. These funds are also used to research prevention and detection techniques for possible future oil spills, in the hope to restore and improve the environmental health of the Gulf of Mexico. The board is unique in that half of the members are selected by the Gulf of Mexico Alliance (GOMA), which then partners with the states of Alabama, Florida, Louisiana, Mississippi, and Texas to appoint the other half in the hope of securing sound ecological collaboration for the region. Shaw was one of four members of LSU's Oil Spill Steering Committee, which oversaw the disbursement of \$10 million in BP research funds awarded to LSU shortly after the *Deepwater Horizon* oil spill. His research has focused on ichthyoplankton taxonomy and ecology and the growth, mortality, habitat requirements, and transport and recruitment mechanisms of larval and young fish on the continental shelf and within estuaries. <http://gulfresearchinitiative.org> 