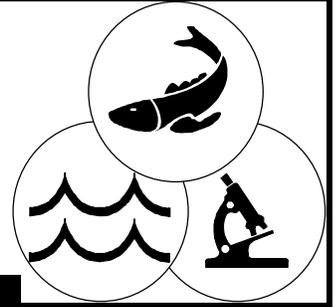


# Fish Health Newsletter

Fish Health Section/American Fisheries Society



June 1998

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## PRESIDENT'S REPORT: IS ANYBODY OUT THERE?

Over the years, the question of Fish Health Section (FHS) advocacy and development of position statements has been raised. We do represent the largest and most established group of aquatic animal health professionals in the United States and one of our charges is to provide leadership on issues germane to our membership. Following an Executive Committee (EXCOM) meeting in Madison, Wisconsin the membership was polled during the business meeting for input and a vote on the issue of Section advocacy. After active debate, the members present at the annual meeting voted unanimously to support an active role for the FHS on issues of importance to the Section and for the EXCOM to develop a process by which to proceed. Randy MacMillan drafted a proposed policy statement that was reviewed and agreed upon by the EXCOM. This policy is now presented to the membership for further discussion.

### DRAFT: FHS Policy Development

*We do represent the largest and most established group of aquatic animal health professionals in the United States and one of our charges is to provide leadership on issues germane to our membership .*

#### Purpose

The following program establishes how the AFS Fish Health Section will develop policy positions regarding fish health issues germane to its membership. The importance of process must be emphasized since the sections membership is diverse. Membership includes private and public aquaculturists, state and federal resource managers, veterinary and non-veterinary diagnosticians and academics. Diverse views may be held regarding fish health matters. Yet, fish health matters require informed debate and, at times, action. This policy development process has been approved by the AFS-FHS Executive Committee to ensure the deliberative and representative consideration is given to policy matters and that policy

development and implementation is subject to membership review.

Policy development must be a participatory process in which all FHS members are encouraged to participate.

#### Policy Development Process

1. The Executive Committee will be responsible for developing and approving policy statements for the FHS.

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2. Policy statements will be developed annually for approval by the Executive Committee at the FHS Annual meeting.
3. Draft policy statements will be identified at least three months prior to the annual meeting. These will be published in the FHS Newsletter and distributed to all members prior to the annual meeting. Members will be encouraged to provide comment on policy and offer alternate language for policy statements.
4. Final language for the policy statements will be developed during the Executive Committee meeting held at the annual meeting.
5. Approval of policy statements will require unanimous decision of the voting members of the Executive Committee. If a unanimous decision is not achieved, it shall be the position of the FHS that the position is too divisive and no position will be taken or it will be modified to achieve a unanimous vote.
6. Policy positions will be published annually in the FHS Newsletter and should be archived.
7. Each policy statement will consist of two parts as follows: background and policy. The background should at a minimum explain the need for a particular policy, and the factors used to define the FHS policy. The policy itself should succinctly identify the policy.
8. Policy needed to be adopted by the FHS prior to the annual meeting should be developed similarly.
  - a. The Executive Committee should identify a need and a draft policy developed.
  - b. This policy draft should be published in the next FHS Newsletter and comment requested. Deadline for receipt of comment should be established and published along with the draft policy.
  - c. Final draft policy should be developed and voted on by the Executive Committee voting members.
  - d. Approved policies should be published in the next FHS Newsletter.
9. Only those policies approved by the Executive Committee can be presented as representing the policy of the FHS.
10. Changes in this policy development process can only be made by unanimous vote of the Executive Committee.
11. It shall be the responsibility of the FHS President or their designee to represent the FHS policy.
12. Challenge to representation must be made in writing to the FHS Executive Committee.
13. Failure to fairly represent the FHS could result in censorship or removal from office pending approval from the remaining members of the Executive Committee.

The membership is encouraged to provide comment to the Executive Committee on this draft process and assist in identifying issues that may be appropriate for developing policy statements. Additionally, we need input on means of rapid communication for issues that may require an immediate response by our organization. Now is the time to band together as a Section and advocate issues of importance to our profession. The alternative may be to exist as a group primarily committed to aquatic animal health research. The choice is yours.

Scott LaPatra, President

## Abstracts from Upcoming *Journal of Aquatic Animal Health*

Editors Note: Below are the *unedited* abstracts from the June 1998 issue (volume 10, number 2) of the *Journal of Aquatic Animal Health*. These peer-reviewed papers were initially presented as talks at a symposium "Pathogens and Diseases of Fish in Aquatic Ecosystems: Implications in Fisheries Management," held in Portland in June 1997. We urge you to check the published article before citing any of these papers.

### **Pathogens and Diseases of Fish in Aquatic Ecosystems Implications for Fisheries Management**

Christine M. Moffitt, Department of Fish and Wildlife Resources, University of Idaho  
Bruce C. Stewart, Northwest Indian Fisheries Commission  
Scott E. LaPatra, Clear Springs Foods, Inc.  
Ray D. Brunson, USFWS, Olympia Fish Health Center  
Jerrri L Bartholomew, Department of Microbiology and Center for Salmon Disease Research, Oregon State University  
James E. Peterson, Montana Department of Fish, Wildlife, and Parks  
Kevin H. Amos, Washington Department of Fish and Wildlife

*Abstract.*--A two-day conference was convened to address the status of information about pathogens and diseases of free-ranging fish populations. In this introduction, we provide background information about the conference and a summary of the presentations and panel discussions.

### **What is "Normative" for Fish Pathogens? A Perspective on the Controversy over Interactions between Wild and Cultured Fish**

Charles C. Coutant, Environmental Sciences Division, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37831-6036, USA

*Abstract.*-- its report, *Return to the River*, the Independent Scientific Group (now called the Independent Scientific Advisory Board), the scientific peer review arm of the Northwest Power Planning Council, advanced the notion of a "normative river ecosystem" as a new conceptual foundation for salmonid recovery in the Columbia River basin. With this perspective, the sum of the best scientific understanding of how organisms and aquatic ecosystems naturally function should be the norm or standard of measure for how we judge the affects of human activities on aquatic systems. For the best likelihood of recovery, key aspects of altered systems should be brought back toward normative (although not necessarily fully back to the historical or pristine state); new alterations should be judged by how much they move key functions away from normative or what might be considered as normal. In this paper, I ask what normative is for fish pathogens and how this concept could help resolve the long-standing disputes between fish culturists and advocates of wild fish in fisheries management. Through literature review and parallels with the evolution of infectious diseases in human populations, I suggest that the concept can be useful for understanding and controlling pathogens and diseases of fish in aquatic ecosystems. One key to avoiding disease outbreaks appears to be maintenance of normal diversity in fish pathogens, intermediate hosts, and immunological types in fish. I encourage further exploration of the normative perspective as a guide to our research and evaluations of pathogens and diseases of fish.

### **Relationships of the Host, Pathogen, and Environment: Implications for Diseases of Cultured and Wild Fish Populations**

R. P. Hedrick, Department of Medicine and Epidemiology, School of Veterinary Medicine,

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University of California, Davis, California 95616, USA

**Abstract.**--Many effects of diseases on cultured fish are known; they are less clear in wild fish populations. Cultured fish represent captive populations that can be subjected to intense scrutiny, with an increasing range of diverse and powerful tools. Disease represents a spectrum from acute mortality to rather benign or inconsequential syndromes all sharing the common feature of a deviation from the normal structure or function of the host.

Understanding these deviations among cultured and wild fish populations and balancing their implications against ecological, economic and political concerns are challenges for both fish health scientists and fisheries managers. The severity of a given disease(s) is dependent on the interaction of numerous variables of the host, the parasite and the environment. To understand diseases and their impacts on fish populations, we must know which variables are important, how we measure them and finally how we assess the results of our measurements. We have perhaps been most successful with variables associated with the pathogen. We often can more easily isolate and scrutinize the pathogen than either the host or the environment. The host variables of importance (for which we lack considerable knowledge) include actions of the immune system in general and specifically the influence of genetics and nutrition on host resistance/susceptibility to disease. Lastly, the contribution of the environment, a nebulous term encompassing everything other than the host and pathogen, is only partly appreciated. While we can measure certain physical and chemical parameters of the environment, we have a poor understanding of the biological-ecological variables that influence host-pathogen interactions. Ultimately, diseases of wild fish must be considered in the context of these complex interactions including numerous physical, chemical, biological and ecological parameters, which may yet be discovered as integral parts of the aquatic habitat.

#### **Host Resistance to Infection by the Myxosporean Parasite Ceratomyxa shasta: A Review**

J. L. Bartholomew, Department of Microbiology and Center for Salmon Disease Research, Oregon State University, Corvallis, OR 97331, USA

**Abstract.**--The capacity of certain salmonids to resist infection and disease caused by the myxosporean *Ceratomyxa shasta* is well known. Observations of differential mortality among strains suggest that intra-species differences in susceptibility developed as a result of selective pressure in waters where the parasite is enzootic. Research efforts have identified resistant strains for use in stocking programs and examined the heritability of the trait. This paper reviews the research on resistance of salmonids to *C. shasta*, the conclusions drawn from these studies and how this information has been applied.

#### **Factors Affecting Pathogenicity of Infectious Hematopoietic Necrosis Virus (IHNV) for Salmonid Fish**

Scott E. LaPatra, Research Division, Clear Springs Foods, Inc., Post Office Box 712, Buhl, Idaho 83316, USA

**Abstract.**- Pathogen is defined as any organism capable of causing disease whereas pathogenicity is the ability of an organism to produce disease. In this context, disease is a definitive morbid process having a characteristic set of symptoms. Furthermore, disease may affect the whole organism or any of its component cells and/or tissues. Regardless of the etiology, disease may either be clinically apparent or subclinical and the outcome is dependent on the pathogen, the properties of the host and the environment where they reside. For example, the virulence of infectious hematopoietic necrosis virus (IHNV) may vary with the age, species and life stage of salmonid fish and water quality parameters including temperature. This review describes factors affecting the virulence of IHNV for salmonid fish and how these factors are involved in the host-pathogen-environment

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interaction that determines occurrence of disease.

### **Whirling Disease in California: A Review of Its History, Distribution, and Impacts, 1965-1997**

John Modin, California Department of Fish and Game, Fish Health Laboratory 2111 Nimbus Road, Rancho Cordova, California 95670, USA

*Abstract.*--*Myxobolus cerebralis*, the causative agent of Whirling disease (WD), has become widely established in wild California salmonid populations since its initial discovery in Monterey County in 1965. Most significant is the occurrence of the parasite in the "blue ribbon" trout waters of Owens Valley water basin of the eastern Sierra. From the Lahontan basin on the north to the Owens Valley 200 miles to the south, the parasite has become well established. In spite of the presence of the parasite, streams of the eastern Sierra are considered by many to support high quality trout populations, attracting thousands of anglers annually to the region. Empirical observations suggest that fish populations in the Owens Valley and *M. cerebralis*-positive waters of the Lahontan and Pacific drainages are healthy. These observations are supported by population data comparing rainbow trout, *Oncorhynchus mykiss*, and brown trout, *Salmo trutta*, populations on Sagehen Creek and the lower Truckee River in the Lahontan basin, and rainbow trout populations in *M. cerebralis*-positive and negative sections of the Carmel River on the central California coast near Monterey. The chronological appearance and distribution of *M. cerebralis* strongly implicates dispersal of live or processed State and commercially produced fish as a major factor in the spread of the parasite in California. Infected anadromous stocks have not appeared to spread detectable levels of *M. cerebralis* into numerous coastal and Bay Area waters. A severe *M. cerebralis* epizootic at the Mt. Whitney State Fish Hatchery in the spring of 1995 confirms the virulent potential of *M. cerebralis* in California. Spores of *M. cerebralis* can no longer be detected in wild populations at two locations following elimination of the source of infection in those waters.

### **Ichthyophthirius multifiliis (Ich) Epizootics in Spawning Sockeye Salmon in British Columbia, Canada**

G. S. Traxler, J. Richard, and T. E. McDonald, Department of Fisheries and Oceans, Pacific Biological Station, Nanaimo, British Columbia V9R 5K6, Canada

*Abstract.*--Epizootics of *Ichthyophthirius multifiliis* occurred in adult prespawning and spawning sockeye salmon *Oncorhynchus nerka* during the 1994 and 1995 spawning seasons, in the Skeena River watershed in northern British Columbia, Canada. Exceedingly high mortalities occurred at Fulton River and three spawning channels adjacent to Babine Lake. During these two years, the infection and subsequent death of prespawning adults resulted in an estimated 153.6 million fewer sockeye fry produced from Fulton River and the three spawning channels adjacent to Babine Lake in comparison with the historical average. The most likely source of the parasite was resident fish in the watershed because several species were found with light infections of *I. multifiliis*. Transmission of the parasite to anadromous sockeye salmon was enhanced by the high density of fish held below the spawning grounds for days or weeks prior to moving into the spawning channel. This is the first report of an epizootic of ichthyophthiriasis in wild spawning salmon.

### **A Case History of Adaptive Management Strategies for Viral Hemorrhagic Septicemia Virus (VHSV) in Washington State**

Kevin Amos, Joan Thomas, and Kathleen Hopper, Washington Department of Fish and Wildlife, 600 Capitol Way North, Olympia, Washington 98501, USA

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*Abstract.*--We examined nearly ten years of data and management decisions by agencies in the Pacific Northwest following the first isolation in North America of a fish pathogen identified as viral hemorrhagic septicemia virus (VHSV). This historical perspective illustrates the problems of managing pathogens in ecosystems that are not self-contained. The responses of management agencies were complicated by the lack of information about relatedness of the local isolate to its European form, by the lack of information of VHSV in marine waters, and the paucity of data regarding the impact of this pathogen on Pacific salmon.

### **Factors Involved in the Dissemination of Disease in Fish Populations**

Paul W. Reno, Coastal Oregon Marine Experiment Station, Department of Microbiology, Oregon State University, Hatfield Marine Science Center  
Newport, Oregon 97365-5296, USA

*Abstract.*--Infectious diseases have been observed in both human and animal populations for millennia. Unlike diseases of "higher" animals, the dispersal of disease in fish populations rarely has been studied quantitatively. However, the principles that govern the spread of diseases of humans and other mammals should, with modification, be applicable to the study of infectious diseases in fishes. Disease in populations is a dynamic phenomenon; fluctuations in prevalence and impact are dependent on the interactions among host, pathogen, and environment. Models of the dynamics of infectious diseases in salmon and other fishes can be constructed and refined to reflect the characteristics of diseases by integrating the most important factors in the process. Among the factors that have been shown to be important in other systems are the "contagiousness" of the pathogen (transmission coefficient,  $\hat{a}$ ), duration of infection, host population density, development of immunity, and efficacy of therapeutants.

### **Healthy Juvenile Sockeye Salmon Reared in Virus-Free Hatchery Water Return as Adults Infected with Infection Hematopoietic Necrosis virus (IHNV): A Case Report and Review of Controversial Issues in the Epizootiology of IHNV**

Theodore R. Meyers, Alaska Department of Fish and Game's Commercial Fisheries Management and Development Division, Post Office Box 25526, Juneau, Alaska 99802, USA

*Abstract.*-- Sockeye salmon *Oncorhynchus nerka* eggs were spawned from a wild broodstock each fall from 1985 to 1989. The eggs and resulting juvenile fish were incubated and reared as separate families in virus-free fresh water. Smolts were released into seawater at the hatchery each following spring when they were about 2-6 g in body weight. At spawning, the yearly prevalence of infectious hematopoietic necrosis virus (IHNV) in the wild broodstock ranged from 0% to 100% while no IHNV disease or virus was ever detected in the progeny at the hatchery. A small number of adult fish from these juvenile releases first returned to the hatchery in 1990. No virus was detected in the 69 fish examined after maturation in virus-free fresh water. In 1991, a greater number of adult fish returned to the hatchery and IHNV was detected at very high titers in fish that matured in both fresh water and seawater. Virus prevalences were as high as 99% in female fish and 40% in males. Potential sources for the IHNV detected in these adult fish are discussed including marine reservoirs, vertical transmission and the carrier state. This case report illustrates the difficulty in eliminating a pathogen from a fish population despite a rigorously controlled rearing environment where the pathogen is seemingly absent.

### **Effect of Pollution on Fish Diseases: Potential Impacts on Salmonid Populations**

(Continued from page 6)

Mary R. Arkoosh, National Marine Fisheries Service, Northwest Fisheries Science Center, Environmental Conservation Division, Hatfield Marine Science Center, 2030 South Marine Science Drive, Newport, Oregon 97365, USA

Edmundo Casillas, National Marine Fisheries Service, Northwest Fisheries Science Center, Environmental Conservation Division, 2725 Montlake Boulevard East, Seattle, Washington 98112, USA

Ethan Clemons and Anna N. Kagley, National Marine Fisheries Service, Northwest Fisheries Science Center, Environmental Conservation Division, Hatfield Marine Science Center

Robert Olson and Paul Reno, Oregon State University, Hatfield Marine Science Center 2030 South Marine Science Drive, Newport, Oregon 97365, USA

John E. Stein, National Marine Fisheries Service, Northwest Fisheries Science Center, Environmental Conservation Division

*Abstract.*—Anthropogenic factors have contributed to the precipitous decline of wild Pacific salmon stocks, although the mechanisms and processes at work are largely unknown. Pollution may be one of these factors. Sediments in estuaries are known to act as repositories for contaminants, and estuaries are important habitats for ocean- and river-migrating salmon. We have shown that juvenile salmon *Oncorhynchus* spp. and their prey bioaccumulate chlorinated hydrocarbons and aromatic hydrocarbons—important classes of toxic xenobiotics. Furthermore, we have shown that exposure to these pollutants can lead to immunosuppression and increased disease susceptibility in juvenile salmon. Whether pollution influences natural disease outbreaks in host populations, including salmon, is currently unknown. It is postulated that the occurrence of disease depends on the interaction of the host, the environment, and the pathogen. Absence of pathogens would reduce the potential for adverse environments to influence disease outbreaks. However, a recent reconnaissance survey of juvenile chinook salmon *Oncorhynchus tshawytscha* from Oregon coastal rivers revealed that pathogens were an integral component in all systems studied, although the prevalence of the pathogens varied. Furthermore, recent studies of natural fish populations have demonstrated that infectious-disease-induced mortality can significantly reduce the size of the host population. By creating adverse environments (e.g., polluted estuaries) which alter the susceptibility of the host to pathogens that are integral and ubiquitous components of the habitat, pollution increases the probability of disease-related impacts on fish populations.

### **Seasonal Occurrence of Virally Induced Skin Tumors in Wild Fish**

R. G. Getchell, J. W. Casey, and P. R. Bowser, Aquatic Animal Health Program, Department of Microbiology and Immunology, College of Veterinary Medicine, Cornell University, Ithaca, New York 14853, USA

*Abstract.*—Seasonal trends in the prevalence of virally-induced skin tumors in a variety of wild fish are reviewed with emphasis on neoplasms in the walleye *Stizostedion vitreum*. The relationship of temperature to mechanisms of virally-induced tumorigenesis and regression in fish is also summarized. Particular emphasis is placed on teleost physiological parameters such as the immune response and endocrinological levels. Other elements of a multifactorial hypothesis for seasonal tumor fluctuations in fish are also discussed.

### **Chinook Salmon Epizootics in Lake Michigan: Possible Contributing Factors and Management Implications**

(Continued from page 7)

Mark E. Holey and Robert F. Elliott, Green Bay Fishery Resources Office, U.S. Fish and Wildlife Service, 1015 Challenger Court, Green Bay, Wisconsin 54311, USA

Susan V. Marcquenski, Bureau of Fisheries Management and Habitat Protection Wisconsin Department of Natural Resources, 101 South Webster Street, Box 7921, Madison, Wisconsin 53707-7921, USA

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Kelley D. Smith, Fisheries Division, Michigan Department of Natural Resources Post Office Box 30028, Lansing, Michigan 48909, USA

**Abstract.**--Stability of the chinook salmon *Oncorhynchus tshawytscha* fishery at high levels in Lake Michigan became questionable after stocks declined dramatically following spring epizootics in which bacterial kidney disease (BKD) was a major factor. Initially stocked in 1967, favorable survival and growth of chinook salmon through the 1970's led to an increase in abundance and popularity with anglers. Returns of chinook salmon improved annually until the late-1980's when, with little warning, spring epizootics reduced the abundance of adult salmon by 50% or more. Reduced alewife *Alosa pseudoharengus* abundance coupled with an increase in chinook salmon density and heavy parasite infection rates was hypothesized to have reduced chinook salmon growth and fitness, increasing their susceptibility to BKD. Evidence of slower growth exists and low food availability is the most likely stressor that triggered the epizootics. Chinook salmon were a major component of the economic development and subsequent hardship of the sport fishing industry on Lake Michigan. Sustaining the chinook salmon fishery at previous levels may require managing for high abundance of alewives, which may be inconsistent with overall fish community goals. The future sustainability and role of chinook salmon needs to be reevaluated in the context of the entire Lake Michigan fish community.

#### **Survey of Salmonid Pathogens in Ocean-Caught Fishes in British Columbia, Canada**

M.L. Kent, G.S. Traxler, D. Kieser, J. Richard, S.C. Dawe, R.W. Shaw, G. Proserpi-Porta, J. Ketcheson, T.P.T. Evelyn, Department of Fisheries and Oceans, Pacific Biological Station, Nanaimo, British Columbia V9R 5K6, Canada

**Abstract.**--A survey of wild fishes captured around marine net-pen salmon farms and from open waters for certain salmonid pathogens was conducted in the coastal waters of British Columbia. Viral hemorrhagic septicemia virus (VHS) was detected in Pacific herring *Clupea pallasii*, shiner perch *Cymatogaster aggregata*, and stickleback *Gasterosteus aculeatus*. Infectious hematopoietic necrosis virus (IHN) was detected in one Pacific herring (collected well away from the farms), and in tube-snouts *Aulorhynchus flavidus* and shiner perch collected near a farm experiencing an IHN outbreak. *Renibacterium salmoninarum* was observed in moribund Pacific hake *Merluccius productus* collected from within a net-pen, and was detected in several ocean-caught salmon. *Aeromonas salmonicida* subsp. *salmonicida* (typical strain) was isolated from a juvenile chinook salmon (*Oncorhynchus tshawytscha*), whereas the atypical strain of this organism was isolated from a ling cod *Ophiodon elongatus*. *Loma salmonae* (Microsporea) was observed in chinook salmon, chum salmon *O. keta*, coho salmon *O. kisutch*, sockeye salmon *O. nerka*, and pink salmon *O. gorbuscha*, all which were captured well away from net-pens. *Loma* spp. (Microsporea) were observed in the gills of shiner perch, ling cod, Pacific tomcod *Microgadus proximus*, Pacific cod *Gadus macrocephalus*, walleye pollock *Theragra chalcogramma*, and sablefish *Anoplopoma fimbria*, all but the first species representing new hosts for *Loma*.

## AQUACULTURE DRUG APPROVALS: OUR CONTINUING COMMITMENT

Thomas A. Bell, Ph.D., USFDA - Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV-130), 7500 Standish Place, Rockville, MD 20855

The arena of aquaculture chemotherapy and the drug approval process for aquatic species has been changing very rapidly and generally in a positive direction. Much of what has been happening has been "behind the scenes" and, hence, the perception of progress and the ensuing attitudes of most stakeholder groups (including the Center for Veterinary Medicine [CVM]) are nowhere as positive as has been the actual progress itself.

I would like to take this opportunity to try to impress upon the aquaculture community the importance of your continued participation in this worthwhile endeavor. However, before embarking on my appeal, I would like to take a few moments to place such continued involvement within the perspective of all of our past efforts.

As many of you are aware, the entire arena of chemotherapy and drug approvals for aquatic species began changing dramatically in the early 1990's. Prior to that time, both the CVM and the aquaculture community had evolved under a program of regulatory discretion with respect to drug use in aquaculture. Before the 1990's CVM considered aquaculture and its use of drugs to be of low priority and generally chose not to take enforcement action against illegal use of drugs (the practice of regulatory discretion). At the same time, and for understandable reasons, the aquaculture industry expanded, in part aided by the use of such illegal drugs. In a few cases, a subsector of the industry may have even developed in large part as a function of the use of an illegal, albeit essential, drug (a possible example might be the use of gender manipulation drugs to develop single-sex populations).

In the early 1990's things changed; aquaculture had grown and its contributions to the U.S. economy and diet increased to the extent that it had, in the opinion of CVM, become a much higher priority industry. CVM's attitude also changed in another way; CVM made significant investments in not only telling our customers why and what we needed to allow for their use of drugs, but also trying to create a two-way street of communication and education. Significant time and resources were expended in an attempt to educate our customers on how and what to provide to CVM, and to learn as much as possible about the industry we had been mandated by law to regulate.

I believe that our collective efforts have paid off. Unfortunately, so much of what has been going on has not been obvious to the casual, or even routine, participant. For a succinct overview of these activities, I would like to merely provide a list of items that are indicative of our concerted undertaking: a) Several large and important coalitions of effort and resources have been formed; b) Such consortia have formulated and articulated to CVM an "Action Plan" for submitting a New Animal Drug Application (NADA = approval); c) As a result of such action plans, real data are now being routinely generated and compiled into data packages worthy of submission under an NADA; d) Such data packages, and a better understanding of the aquaculture industry, have prompted pharmaceutical firms (both large and small) to become interested and involved; e) The pharmaceutical industry (with some involvement by CVM) has become involved in efforts to internationally harmonize the data required to support the drug approvals in several countries; and f) The ultimate result is the submission to CVM of legitimate NADAs or NADA technical sections (an example of a technical section would be the entire data package submitted to support a claim that the drug is effective for a particular use). In addition to the results of our efforts relative to routine drug approvals, CVM has, with major and essential contributions by the aquaculture industry (and other minor species industries), developed a set of proposals to be submitted to Congress that outline innovative

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means of increasing the availability of legal drugs for use with aquatic species and all other minor species (e.g., zoo animals, gamebirds and goats). This draft document, entitled: "Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses" ("MUMS" document), was made public and available for comments via CVM's website ([www.fda.gov/cvm/](http://www.fda.gov/cvm/)). This document proposes general incentives and mechanisms outside of the traditional NADA process to increase involvement in the drug approval process; the anticipated net result being increased numbers of drugs that can be legally used on all aquatic species (as well as increased legal use for other minor species).

Adding to the previous paragraph by looking even further behind the scenes, I offer the following information in the hope that it will foster an even better appreciation of the real progress that has been made. At the present moment, we at CVM have either a commitment to pursue an INAD/NADA or have, under review, complete NADA packages or NADA technical sections for the following drugs (those underlined are commitments only): a) hCG as a spawning aid for all fish - InterVet, b) formalin expansion of use to include all fish - Western Chemical, c) erythromycin for BKD in all salmonids - no sponsor, d) copper sulfate as a broad spectrum microbicide for all fish - Phelps Dodge, e) 17-methyltestosterone for gender manipulation in tilapia - Rangen Feeds, f) OTC for bacterial diseases in penaeid shrimp - no sponsor, g) Salmosan (azamethiphos) for sea lice in salmonids - Novartis, h) Aqui-S anesthetic for salmonids - Aqui-S New Zealand, Limited, and i) Fumagillin for whirling disease (salmonids) and hamburger gill (catfish) - Sanofi and j) Florfenicol for furunculosis - Schering-Plough. Interest in any of the aforementioned products should first be directed to CVM. It should be understood that these products represent only those for which we have permission to disclose information, and that there are other INADs/NADAs for which all information must remain, for now, confidential.

In spite of what I, and many others both inside and outside of CVM, believe to be real progress, affected in large part by your involvement, there are some very serious concerns within our entire community that may become counter-productive to the drug approval process. When I say the "entire community," I mean not only aquaculturists outside of CVM, but also those of us inside CVM. In general, there is an overall frustration with a lack of "return on investment." In some instances this frustration, coupled with dwindling resources (not only within the public sector, but the private sector as well) may result in a disinvolvement with the INAD/NADA process; we have gained so much and to many of us to even think about not continuing ongoing projects to completion is beyond comprehension. To exacerbate the general frustration, we at CVM are now faced with the added dilemma of increased workload (I guess some might say we brought it upon ourselves) compounded by real reductions in human resources.

Why, might you ask, given what I have just said about resources, etc. would I implore you to continue with your involvement in the INAD/NADA process, to continue to work within consortia or other consolidated efforts to generate pivotal data, to continue to publicly support the MUMS document, to continue to monetarily support consolidated efforts such as the IAFWA (International Association of Fish and Wildlife Agencies), and to generally maintain your commitment to gaining drug approvals for aquatic species? Well, I believe that the answer is quite simple. We are all involved in the production of aquatic species, which not only provide a growing portion of our diet, but also otherwise significantly impact on our lives. We all must play a part in assuring that the drug products we use for these animals are effective for their claimed uses, safe to the animals, safe to those of us who administer the drugs, safe to the environment and most importantly for use in food animals, safe to those of us who consume products derived from their edible portions.

The present drug approval process, as imperfect as it may be, is the only alternative presently available. We have all worked very hard to make it as user-friendly and flexible as the law will allow. We have worked equally hard to try to change the process (the MUMS document). It

## UPCOMING MEETINGS

### SUPER SYMPOSIUM ON THE HORIZON!

The **Third International Symposium on Aquatic Animal Health**, to be held in Baltimore August 30 -September 3, is shining brightly upon the horizon! This meeting, the third in the series following Vancouver in 1988 and Seattle in 1992, will also incorporate the annual meeting of the AFS -Fish Health Section. The symposium will be a unique opportunity for professionals and students working in the aquatic animal health arena to gather together. Our abstract and early registration deadline passed in mid-March, and yielded abstracts for approximately 200 oral contributions and 100 posters - a very promising beginning! Participants are expected from throughout the world, and will present work concerning a great diversity of animals including shellfish, fish, turtles, and marine mammals. Our scientific sessions will include plenary lectures, oral presentations, a poster sessions, and special sessions on topics as diverse as "The use of advanced technologies in aquatic animal health management", "Integrated monitoring of disease, mortality and the environment:development of a global database", and "Toxic algae and dinoflagellates".

The meeting will also feature microscopes to enable participants to bring material for informal review with colleagues, exhibitions of recently published books, and an exhibition of biological illustrations. The symposium has been approved for continuing education credit for veterinarians. Our social program will include an icebreaker reception, an evening at the National Aquarium in Baltimore, a sumptuous banquet, behind the scenes tours of aquatic animal health facilities in the Baltimore area, and optional tours to Washington D.C., and to the art museums and galleries of Baltimore. For those of you who have sent abstracts and/or early registration, please note that in May we plan to send you notification of acceptance/rejection of your abstract (hopefully the former!), and acknowledgment of your payment. Please continue to make your preparations! If you have not already registered for the meeting, there is still time to do so, and we ask that you spread the news of the meeting to colleagues who may not yet have heard about it. We look forward to welcoming you to Baltimore in August! If you wish to contact the symposium office, we can be reached at:

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### FISH HEALTH SECTION/ ADVANCED TECHNOLOGIES WORKGROUP

The advanced technologies workgroup is focused on developing quality assurance \ quality control guidelines for laboratories involved with aquatic animal health. Draft guidelines for the different sections of the document are due by the second week of July. We plan to present our recommendations to the section at the annual meeting in September. The workgroup believes the section needs a standing committee to peer review QA\QC documents from laboratories to maintain consistency and continuity.

The workgroup consists of Jim Peterson, Pete Walker, John Cole, Phil Klesius, Bill Keleher and Joe Marcino. Once the QA\QC document is completed we intend to assist in procedures to validate new diagnostic procedures.

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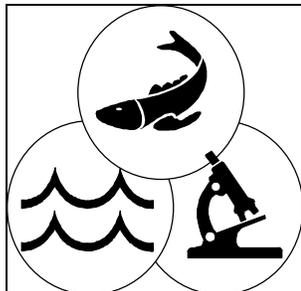
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**Deadline for next issue:**  
**July 24, 1998**

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Fish Health News

## **Fish Health Newsletter - Editorial Policy**

The *Fish Health Newsletter* is a quarterly publication of the Fish Health Section of the American Fisheries Society. Submissions on any topic of interest to fish health specialists and preliminary case reports are encouraged with the understanding that material is not peer reviewed. Abstracts submitted to the *Journal of Aquatic Animal Health* are also encouraged. Articles should not exceed two newsletter pages and should not have more than five references. Submissions *must* be formatted in WordPerfect 6.x (preferred) or other major Windows word processors, and can be sent by electronic mail or via 3.5" floppy disk to the content editor's address below:

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