



## Why INADs are a fish farmer's best friend

BOZEMAN, MT – Fish farmers can use Investigational New Animal Drug (INAD) exemptions to medicate their fish with certain drugs that have not yet been approved for use, as long as they follow use-guidelines and collect data that can contribute to the eventual approval of the drug.

At this year's Aquatic Animal Drug Approval Partnership (AADAP) meeting, which was held July 27-30, INAD Coordinator Bonnie Johnson summarized 15 years worth of INAD data collection.

I was so impressed with the number of aquaculturists who had contributed to the program and with the number of fish lives saved that I had to put the information in front of you.

The AADAP office at the US Fish and Wildlife Service's Bozeman Fish Technology Center is somewhat understaffed these days, at least compared to previous years, so the current crew has had to scramble a bit keeping up with all the data that fish farmers are contributing.

But Bonnie still was able to present some amazing statistics.

From 1999 to 2014, roughly 1.3 billion fish were treated with various drugs under INAD exemptions. It's an incredible figure when you try to visualize that many animals.

Five hundred seventy-one federal, state, private, tribal, and university facilities participated in the effort, all generating much-needed data to be compiled for the potential approval of new disease treatment options.

The reason this program is so important is because fish are considered a "minor species" in the drug world, and very few "approved" drugs are on the market right now to treat minor species.

This situation has seriously hampered the aquaculture

## FISH HEALTH NOTES

BY ROD GETCHELL



industry in the past, which is why being able to treat fish under an INAD exemption has been a welcome step forward.

Clearly, fish farmers and hatchery personnel are willing to do the required data collection, hoping the information will help lead to more drugs being approved and readily available in the future.

If a pharmaceutical company had to pay for this kind of research, new options for disease treatments would never move forward in the long approval process.

Bonnie graciously let me use some of her slides to show you the breakdown of the fish species most studied through the National INAD Program and where the work was completed (see figures).

### History

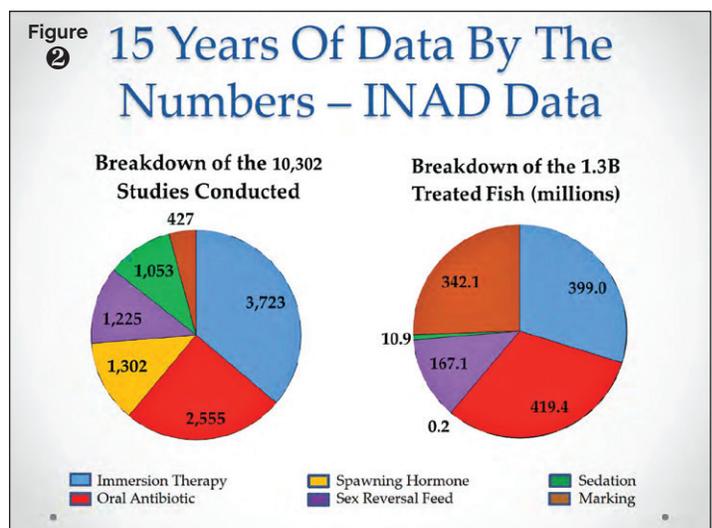
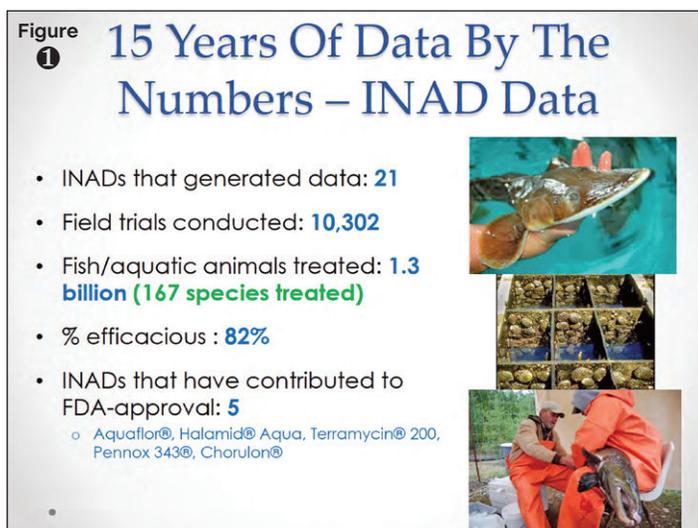
The National INAD Program was started in 1998.

Contributors and users include all US aquaculture facilities, field biologists, and researchers.

As funding to AADAP has been cut, INAD participant costs have had to be recovered through user fees.

The AADAP folks at US Fish and Wildlife work with US Food and Drug Administration (FDA) professionals and drug sponsors from the pharmaceutical industry who ultimately must get these new therapeutants licensed.

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The types of studies conducted under the INAD exemptions have included immersion therapies, oral antibiotics, spawning hormones, sex reversal treatment, sedation, and marking for later age and/or survival determination.

The life stage of fish studied follows the trend you would expect. Younger, more susceptible but easier-to-treat fry and fingerlings are more frequently dosed under INAD exemptions.

The data collected at fish hatcheries throughout the country, under real life situations, provides invaluable information for regulators who must determine whether the suggested new compounds are indeed effective in the manner in which they are used.

Important data on the safety of the chemicals or therapeutics also is collected.

Drugs are not approved until proven safe.

Regulatory authorities take a precautionary approach to any substances that may enter the environment or be consumed by people or have an adverse effect on fish being raised for food.

Fish folks are just as careful in protecting the health of the fish they raise.

The American Fisheries Society (AFS) recently pointed out that the most common water treatments applied in hatcheries are low doses of hydrogen peroxide, which breaks down to carbon dioxide and water, and chloramine, a common disinfectant.

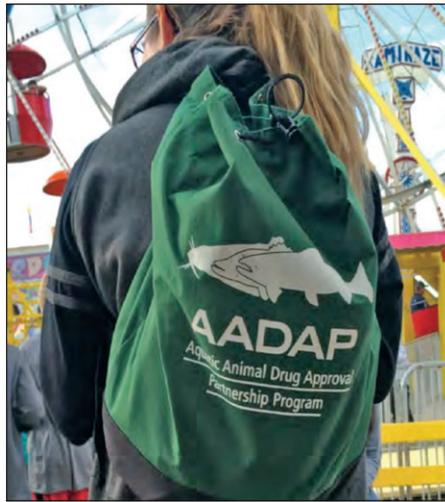
AFS also makes the case that hatchery effluents are minor compared to the pharmaceutical and personal care products that enter our country's waterways.

### Why are INADS important?

Without the assistance of all these users and the effort that AADAP expends to collate and organize this data, most drug sponsors could not afford to conduct these required safety and effectiveness studies.

It comes down to the bottom line really.

If a drug company cannot recover its research and



USFWS photo

Bonnie Johnson wearing the AADAP bag.

development costs when it puts a product on the market, the company simply will not expend the effort in the first place.

Inequities in drug availability represent serious management and economic problems for producers of minor animal species like fish.

These drug trials show researchers and FDA what does and doesn't work in specific fish species that run into trouble at our local fish farms or agency hatcheries.

The "One Health" folks here at the Cornell veterinary college where I work believe the health of humans is connected to the health of animals and the environment.

The science behind animal health and human health is really no different.

Whatever our mission is, we need to monitor and control health threats.

Our own medical doctors collect the same kind of information as those of you who go through the trouble to collect data to send to Bonnie in Bozeman.

INADs are a lifesaver for the small farmer and the large establishment.

### Learn more

The AADAP website can be found at <http://www.fws.gov/fisheries/aadap/home.htm>. It contains much more information about INADs, the National INAD Program, and general drug use guidance.

However, the website does need a bit of updating. So if you see or hear conflicting information about the program, don't hesitate to contact Bonnie Johnson herself for clarification. She can be reached by e-mail at [bonnie\\_johnson@fws.gov](mailto:bonnie_johnson@fws.gov).

One thing I am not conflicted about is the dedication of the AADAP staff in Bozeman.

They contribute much to the health of US fish stocks and should be lauded for their largely unheralded efforts.

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