



Introduction to AQUIS: A Potential Zero-withdrawal Fish Anesthetic

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Aquatic Animal Drug Approval Workshop
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Presented by:

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Fish Anesthetic Background

- **Finquel and MS-222 approved, but have a 21-d withdrawal**
 - Safe and effective anesthetic
 - However, 21-d withdrawal period limits:
 - Use of artificially spawned fish where fish are released
 - Use of carcasses as fish meal or for nutrient enhancement
 - Rested harvest
- **No legally approved zero withdrawal anesthetic**
- **Fish culturists and fisheries managers need a zero-withdrawal anesthetic**

Why is AQUI-S® a candidate zero-withdrawal anesthetic?

- Fish anesthetic developed by AQUI-S New Zealand, LTD
- Synthetic 54% isoeugenol
- Isoeugenol is cleared for use in human food (21CFR 172.515)
- Approved in New Zealand, Australia, and Chile for use on food fish (no withdrawal period required)
- Candidate for US approval as a “zero-withdrawal” anesthetic



AQUI-S[®]

Aquatic Anaesthetic

**for use in the handling and harvesting
of fish and other seafood**

ACTIVE INGREDIENT : 540 g/L isoeugenol

Why Not Clove Oil?

- Clove oil is 85 – 95% eugenol (isoeugenol & methyleugenol)
- Clove oil is not clove oil is not clove oil is not.....
- Clove oil is GRAS as a substance added directly to human food; eugenol is GRAS in animal feed
- Eugenol is an equivocal carcinogen; methyleugenol is carcinogenic to rodents
- Neither clove oil nor eugenol is approved as a new animal drug
- No sponsor willing to pursue FDA-approval of clove oil

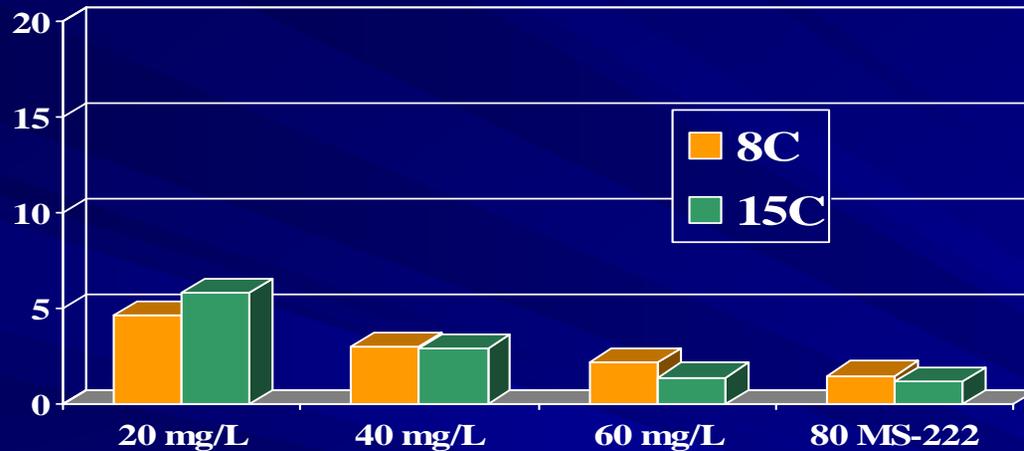
Why not get a zero-withdrawal for MS-222?

- Sponsor not willing to invest \$\$ to redo toxicology or residue depletion studies
- Target animal safety studies would likely result in greatly reduced approved treatment doses
- No plans to further test MS-222

Is AQUI-S[®] a safe and effective anesthetic?

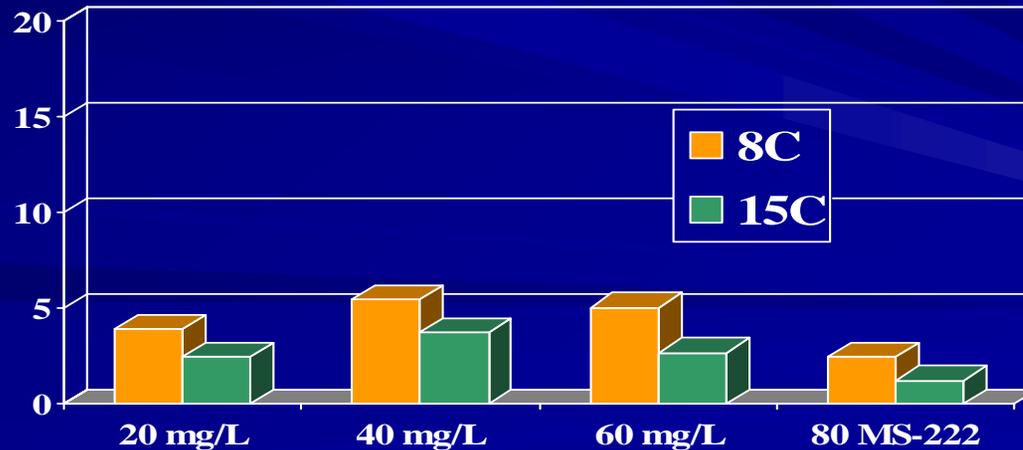
- **Yes!**
- **For short-term sedation (handleable)?**
 - Yes, and all efficacy studies have been completed
- **For long-term sedation (long-hauling)?**
 - Yes, but no studies are yet planned to demonstrate this
- **Is there an adequate margin of safety so I won't kill my fish if I leave them in too long?**
 - Yes, for short-term sedation at lower doses
 - Uncertain for long-term sedation

Mean time to handleable and recovery from handleable (RBT)



Time to handleable

Time to recovery



Pivotal Studies completed

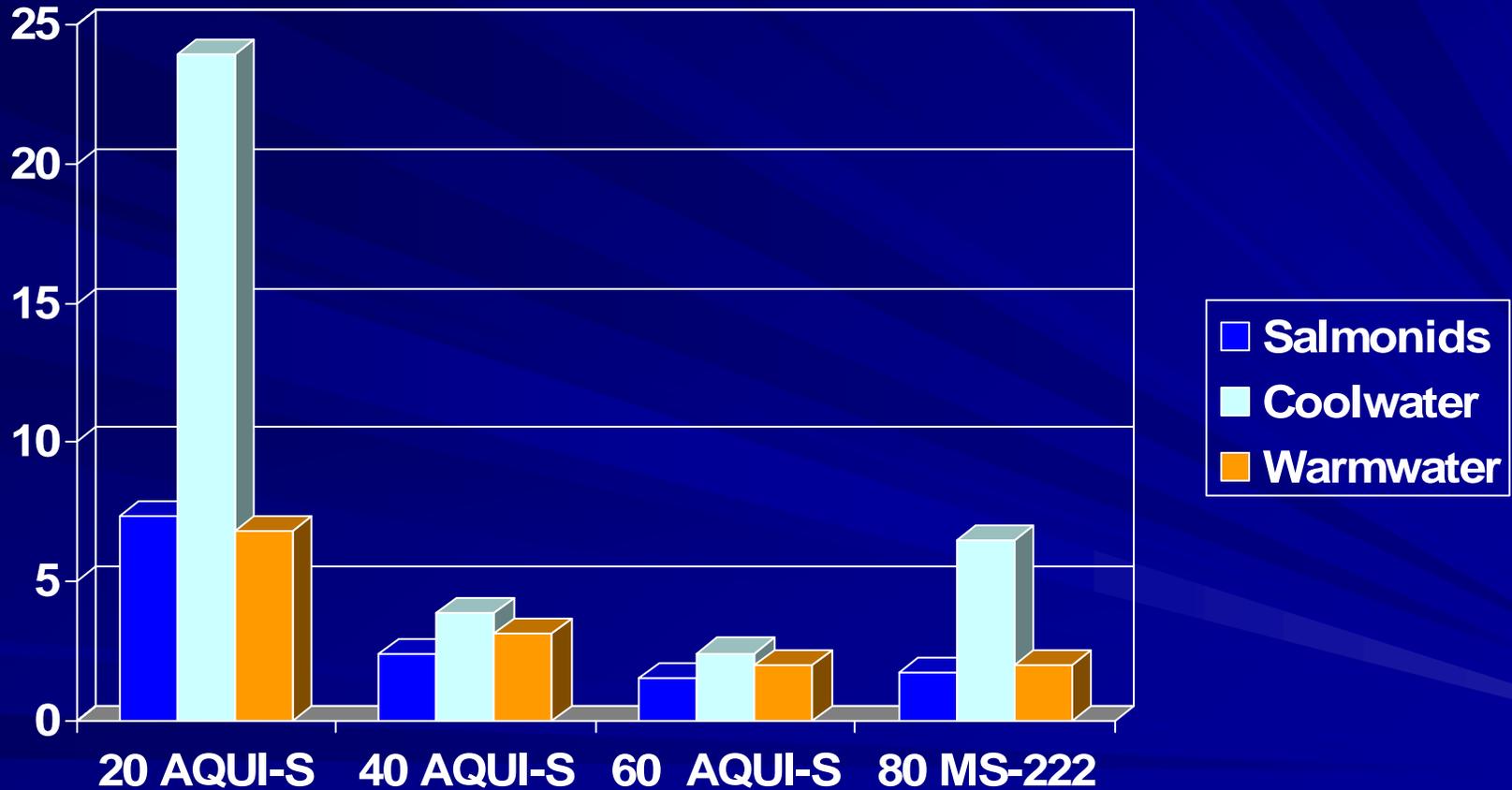
- Rainbow trout (fry & subadult)
- Steelhead trout (adult)
- Chinook salmon (fry & subadult)

- Largemouth bass (fingerling & adult)
- Smallmouth bass (fingerling and adult)
- Walleye (fry and juvenile)

- Tilapia (juvenile and adult)
- Channel catfish (juvenile & adult)
- Hybrid striped bass (fingerling, juvenile & adult)

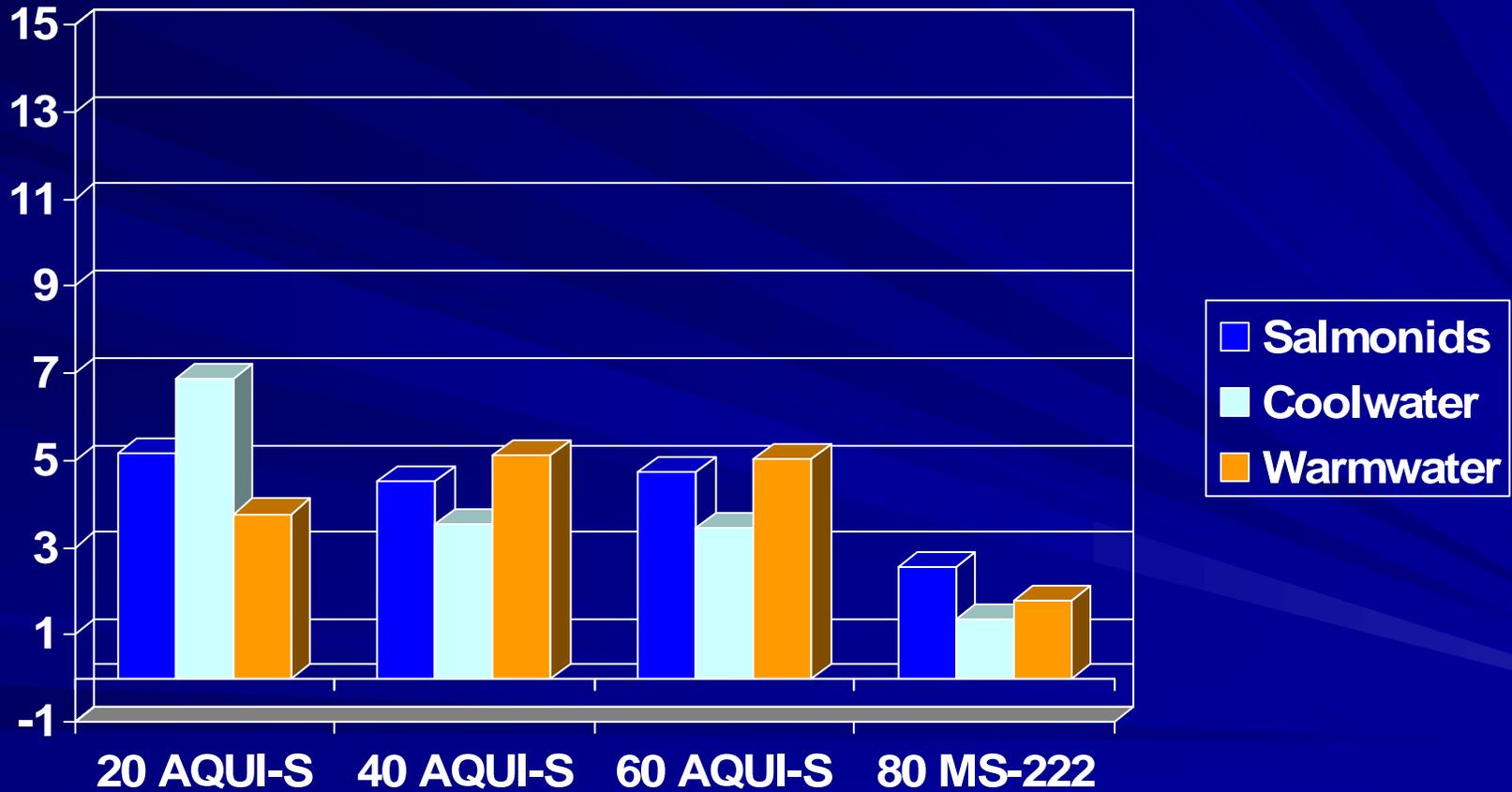
Pivotal Studies

Summary Time to handleable



Pivotal studies

Summary Time to recover
from handleable



Status of AQUI-S®

- Progress is being made to gain FDA-approval of AQUI-S® (see Status of Drug Approvals)
- All pivotal efficacy testing done for the following claim: to sedate all freshwater fish to the handleable stage of anesthesia
- Initial label claim will most likely be for all freshwater-reared salmonids
- Initial approval still a few years out
- Participate in AADAP's AQUI-S® INAD now

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- **A short video to show:**
 - **How to prepare an AQUI-S[®] bath solution**
 - **Differences between sedating cutthroat trout with AQUI-S[®] and MS-222**